

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CLAUS GRABOWSKY, Derivatively on Behalf
of Nominal Defendant INTEGRA
LIFESCIENCES HOLDINGS CORPORATION,

Plaintiff,

v.

CARRIE L. ANDERSON, PETER J. ARDUINI,
GLENN G. COLEMAN, ROBERT T. DAVIS,
JR., JAN D. DE WITTE, LEA KNIGHT, STEVE
LEONARD, JEFFREY A. MOSEBROOK,
STUART M. ESSIG, KEITH BRADLEY,
SHAUNDRA D. CLAY, BARBARA B. HILL,
JEFFREY A. GRAVES, RENEE W. LO,
RAYMOND G. MURPHY, CHRISTIAN S.
SCHADE, LLYOD W. HOWELL, JR.,
RHONDA GERMANY BALLINTYN, and
DONALD E. MOREL, JR.,

Defendants,

and

INTEGRA LIFESCIENCES HOLDINGS
CORPORATION,

Nominal Defendant.

Case No. 3:25-cv-01399

JURY TRIAL DEMANDED

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

Plaintiff Claus Grabowsky (“Plaintiff”), by and through his undersigned attorneys, brings this derivative complaint for the benefit of nominal defendant Integra LifeSciences Holdings Corporation (“Integra” or the “Company”), against its Board of Directors (the “Board”) and certain of its executive officers seeking to remedy Individual Defendants’ (defined below) breaches of fiduciary duties and violations of federal law. Plaintiff alleges the following

based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Defendants' publicly available documents, conference call transcripts and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, press releases published by and regarding Integra, legal filings, news reports, securities analysts' reports about the Company, filings in the securities class action captioned *In re Integra LifeSciences Holdings Corporation*, Case No. 3:23-cv-20321-MAS-TJB (D.N.J.) (the "Securities Class Action"), and other publicly available information.

NATURE OF THE ACTION

1. This is a shareholder derivative action brought by Plaintiff on behalf of Integra against certain of its current and former officers and members of the Company's Board (the "Individual Defendants")¹ for breaches of their fiduciary duties between at least March 11, 2019 and July 28, 2024, inclusive (the "Relevant Period"), and violations of federal securities laws, as set forth below.

2. Founded in 1989, Integra is a global medical technology company that has developed numerous product lines, including an engineered collagen technology platform used to repair and regenerate tissue.

¹ The Individual Defendants are Carrie L. Anderson ("Anderson"), Peter J. Arduini ("Arduini"), Glenn G. Coleman ("Coleman"), Robert T. Davis, Jr. ("Davis"), Jan D. De Witte ("De Witte"), Lea Knight ("Knight"), Steve Leonard ("Leonard"), Jeffrey A. Mosebrook ("Mosebrook"), Stuart M. Essig ("Essig"), Keith Bradley ("Bradley"), Shaundra D. Clay ("Clay"), Barbara B. Hill ("Hill"), Jeffrey A. Graves ("Graves"), Renee W. Lo ("Lo"), Raymond G. Murphy ("Murphy"), Christian S. Schade ("Schade"), Lloyd W. Howell, Jr. ("Howell"), Rhonda Germany Ballintyn ("Ballintyn"), and Donald E. Morel, Jr. ("Morel"). "Defendants" means Integra and the Individual Defendants.

3. The Company's products are sold in more than 130 countries through a direct sales force as well as distributors and wholesalers. Integra manufactures and sells medical technologies and products in two reportable business segments: Codman Specialty Surgical and Tissue Technologies. The Company's Tissue Technology segment focuses on complex wound surgery, surgical reconstruction, and peripheral nerve repair and consists of five unique regenerative technology areas.

4. The Company's most lucrative portfolio of products are its regenerative surgical tissue products, also known as "biologic mesh."

5. Throughout the Relevant Period, the Individual Defendants made materially false and misleading statements related to the Company's compliance with the U.S. Food and Drug Administration's ("FDA") current Good Manufacturing Practices ("cGMP"). Specifically, the Individual Defendants assured investors that the Company was compliant with cGMP in its manufacturing of its biologic mesh products and downplayed the cGMP deficiencies found by the FDA throughout the Relevant Period.

6. However, in reality, Integra systemically violated cGMP in its manufacturing of biologic mesh and failed to take the proper steps to remediate these violations. Indeed, just before the start of the Relevant Period, on March 6, 2019, the FDA issued a warning letter that outlined numerous cGMP violations it found at the Company's manufacturing facility located in Boston, Massachusetts, which was its exclusive site for manufacturing biologic mesh (the "Boston Facility"). Throughout the Relevant Period, the Company continued to receive warnings from the FDA that the Boston Facility was violating the cGMP regulations, which eventually resulted in the recall of multiple of Integra's medical devices and a shutdown of the Boston Facility.

7. Despite this, the Individual Defendants took no meaningful steps to remediate the

cGMP violations and continuously assured investors that the Company “adheres to good manufacturing practices,” that the Company was on track with its remediation efforts, and that the cGMP deficiencies identified by the FDA would not have a significant impact on Integra’s business.

8. The truth began to emerge on February 28, 2024, when the Company announced that Integra was experiencing significant declines in its financial performance due to the earlier announced forced shutdown and remediation at the Boston Facility. This same day, the Company also unexpectedly revealed that Defendant De Witte was leaving the Company.

9. On this news, the Company’s stock price fell \$5.60 per share, or approximately 13%, to close at \$38.67 per share on February 28, 2024.

10. Then, on May 6, 2024, the Company announced that the shutdown of the Boston, which was originally announced in April 2023, would need to be extended for another seven months, bringing the total shutdown time to *over a year and a half*.

11. On this news, the Company’s stock price fell \$5.75 per share, or approximately 20%, to close at \$23.14 per share on May 6, 2024

12. The truth about the Company’s cGMP violations fully emerged on July 29, 2024, when Integra revealed that there were cGMP deficiencies and shipping holds across *all* of the Company’s facilities, which required the Company to implement a company-wide “compliance master plan” to address quality systems and cGMP deficiencies. As detailed herein, this compliance master plan would have a significant financial impact on Integra.

13. On this news, the Company’s stock price fell \$6.01 per share, or approximately 19%, to close at \$25.42 per share on July 29, 2024.

14. As set forth herein, the Individual Defendants breached their fiduciary duties by

issuing, causing the issuance of, and/or failing to correct the materially false and/or misleading statements and omissions of material fact to the investing public. Specifically, the Individual Defendants failed to disclose to investors that: (a) the Company was not taking meaningful efforts to address the systemic cGMP deficiencies at the Boston Facility; (b) the Company did not comply with cGMP in the manufacturing of SurgiMend, PriMatrix, and other extracellular bovine matrix (“EBM”) products; (c) the Company did not have proper internal mechanisms and processes in place to ensure compliance with cGMP; (d) the cGMP violations that led to the FDA investigations and findings impacted the Company’s ability to manufacture EBM products at the Boston Facility; (e) the Company did not have effective risk oversight mechanisms in place; and (f) as a result of the foregoing, the Company’s public statements regarding its business, operations, and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

15. As a result of the foregoing, the Securities Class Action was filed against the Company and Defendants Anderson, Arduini, Coleman, Davis, De Witte, Knight, Leonard, and Mosebrook on September 12, 2023, in the United States District Court for the District of New Jersey.

16. As a direct and proximate result of the Individual Defendants’ misconduct, the Company has incurred significant financial losses, including the cost of defending and paying class-wide damages in the Securities Class Action, as well as additional losses, including reputational harm and loss of goodwill.

17. Moreover, in light of the breaches of fiduciary duty engaged in by the Individual Defendants, most of whom are the Company’s current directors, their collective engagement in fraud, the substantial likelihood of the directors’ liability in this derivative action and Defendants’ liability in the Securities Class Action, their being beholden to each other, their longstanding

business and personal relationships with each other, and their not being disinterested and/or independent directors, a majority of Integra's Board cannot consider a demand to commence litigation against themselves and the other Individual Defendants on behalf of the Company with the requisite level of disinterestedness and independence. Accordingly, Plaintiff did not make a demand on the Board because, as further detailed herein, demand would be a futile and useless act.

JURISDICTION AND VENUE

18. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and Section 27 of the Securities Exchange Act of 1934 (the "Exchange Act") over the claims asserted herein for violations of Section 14(a) of the Exchange Act (15 U.S.C. § 78n(a)) and Rule 14a-9 (17 C.F.R. § 240.14a-9) promulgated thereunder by the SEC.

19. Plaintiff's claims also raise a federal question pertaining to the claims made in the Securities Class Action based on violations of the Exchange Act.

20. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1337(a).

21. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

22. In connection with the acts, conduct and other wrongs complained of herein, the Individual Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, the United States mail, and the facilities of a national securities market.

23. Venue is proper in this District pursuant to Section 27(a) of the Exchange Act and 28 U.S.C. § 1331 because Integra maintains its principal executive offices in this District, Defendants have conducted business in this District, a substantial portion of the acts and omissions alleged herein, including the dissemination of materially false and misleading information,

occurred in this District, Defendants have received substantial compensation in this District by engaging in numerous activities that had an effect in this District, and the Securities Class Action is pending in this District.

PARTIES

Plaintiff

24. Plaintiff is, and has been at all relevant times, a continuous shareholder of Integra.

Nominal Defendant

25. Nominal Defendant Integra is a Delaware corporation with its principal executive offices located at 1100 Campus Road, Princeton, New Jersey 08540. Integra's common stock trades on the NASDAQ Global Select Market under the ticker symbol "IART."

Individual Defendants

26. Defendant Anderson served as Executive Vice President and Chief Financial Officer ("CFO") of the Company from June 2019 until February 2023. According to the Company's public filings, Defendant Anderson received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$2,405,936
2020	\$2,060,755
2021	\$2,636,663
2022	\$2,951,694
2023	\$67,280

27. Defendant Arduini served as Chief Executive Officer ("CEO") and a director of the Company from January 2012 until December 2021. Prior to this, from October 2010 until December 2011, Arduini served as President and Chief Operating Officer ("COO") of the Company. According to the Company's public filings, Defendant Arduini received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$7,859,423
2020	\$7,740,699
2021	\$9,839,221

28. Defendant Coleman served as COO of the Company from June 2019 until September 2022. Prior to this, from May 2014 until June 2019, Coleman served as Corporate Vice President and CFO of the Company. According to the Company's public filings, Defendant Coleman received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$3,120,418
2020	\$2,827,990
2021	\$3,537,468
2022	\$4,425,564

29. Defendant Davis has served as Executive Vice President and President of the Tissue Technologies division of the Company since March 2020. Davis has also served as the Company's Corporate Vice President and President of the Orthopedics and Tissue Technologies division since December 2016. Prior to this, Davis served in various executive roles at the Company between July 2012 and December 2016. According to the 2024 Proxy (defined herein), Davis's responsibilities include leadership of sales, commercial operations, marketing and strategy, product development, regulatory affairs, quality assurance, manufacturing services and repair, business development of the regenerative tissue portfolio of products. According to the Company's public filings, Defendant Davis received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$1,390,401
2020	\$1,365,577
2021	\$1,957,844
2022	\$1,932,535
2023	\$1,422,883

30. Defendant De Witte served as President, CEO, and a director of the Company from December 2021 until January 2025. According to the Company's public filings, Defendant De Witte received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2021	\$251,773
2022	\$9,319,913
2023	\$6,388,756

31. Defendant Knight has served as Executive Vice President and CFO of the Company since June 2023. According to the Company's public filings, Defendant Knight received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2023	\$1,673,147

32. Defendant Leonard has served as Vice President, Global Operations and Supply Chain of the Company since August 2020. Previously, Leonard served as the Company's Senior Vice President of Operations from May 2019 until August 2020.

33. Defendant Mosebrook has served as Principal Accounting Officer of the Company since October 2017 and as Senior Vice President, Finance of the Company since January 2020. Previously, Mosebrook served as the Company's Principal Financial Officer from February 2023 until June 2023. Mosebrook served in various roles at the Company since he joined in 2006, including as a Vice President and the Corporate Controller from September 2014 until January 2020. According to the Company's public filings, Defendant Mosebrook received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2023	\$1,253,294

34. Defendant Essig has served as Executive Chairman of the Company since 2012 and as a director of the Company since 1997. According to the Company's public filings, Defendant

Essig received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$347,533
2020	\$395,028
2021	\$400,030
2022	\$400,034
2023	\$422,520

35. Defendant Bradley has served as a director of the Company since 1992. Bradley also serves as Chair of the Company's Compensation Committee and as a member of the Company's Nominating and Corporate Governance Committee and Finance Committee. According to the Company's public filings, Defendant Bradley received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$265,052
2020	\$256,277
2021	\$280,008
2022	\$298,809
2023	\$306,313

36. Defendant Clay has served as a director of the Company since 2021. Clay also serves as a member of the Company's Audit Committee. According to the Company's public filings, Defendant Clay received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2021	\$284,576
2022	\$280,050
2023	\$260,038

37. Defendant Hill has served as a director of the Company since 2013. Hill also serves as Chair of the Company's Nominating and Corporate Governance Committee. According to the Company's public filings, Defendant Hill received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$305,059
2020	\$305,059
2021	\$320,045
2022	\$320,050
2023	\$342,539

38. Defendant Graves has served as a director of the Company since 2023. Graves also serves as a member of the Company's Compensation Committee. According to the Company's public filings, Defendant Graves received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2023	\$90,697

39. Defendant Lo has served as a director of the Company since 2022. Lo also serves as a member of the Company's Compensation Committee. According to the Company's public filings, Defendant Lo received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2022	\$191,776
2023	\$297,538

40. Defendant Murphy has served as a director of the Company since 2009. Murphy also serves as a member of the Company's Audit Committee, Nominating and Corporate Governance Committee, and Finance Committee. According to the Company's public filings, Defendant Murphy received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$247,545
2020	\$295,027
2021	\$300,027
2022	\$281,260
2023	\$297,538

41. Defendant Schade has served as a director of the Company since 2006. Schade also serves as Chair of the Company's Audit Committee and Finance Committee. According to the Company's public filings, Defendant Schade received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$298,802
2020	\$271,277
2021	\$295,027
2022	\$313,800
2023	\$293,280

42. Defendant Howell served as a director of the Company from March 2013 until February 2021. Howell also served as a member of the Company's Nominating and Corporate Governance Committee and Finance Committee. According to the Company's public filings, Defendant Howell received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$265,052
2020	\$256,277

43. Defendant Ballintyn served as a director of the Company from January 2019 until May 2022. Ballintyn also served as a member of the Company's Compensation Committee. According to the Company's public filings, Defendant Ballintyn received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$339,625
2020	\$256,277
2021	\$280,045

44. Defendant Morel served as a director of the Company from August 2013 until May 2023. Morel also served as Chair of the Company's Compensation Committee. According to the

Company's public filings, Defendant Morel received the following in compensation from the Company during the Relevant Period:

Year	Total Compensation
2019	\$280,045
2020	\$286,277
2021	\$295,027
2022	\$276,260
2023	\$45,000

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

45. By reason of their positions as officers and/or directors of Integra, and because of their ability to control the business and corporate affairs of Integra, the Individual Defendants owed Integra and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Integra in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Integra and its shareholders.

46. Each director and officer of the Company owes to Integra and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligation of fair dealing.

47. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Integra, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

48. To discharge their duties, the officers and directors of Integra were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

49. Each Individual Defendant, by virtue of his or her position as a director and/or officer owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good

faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and/or officers of Integra, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

50. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, financial statements, products, management, internal controls, earnings, and present and future business prospects, including the dissemination of false and/or materially misleading information regarding the Company's business, prospects, and operations, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful, accurate, and fairly presented information.

51. To discharge their duties, the officers and directors of Integra were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Integra were required to, among other things:

(i) Ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of New Jersey and the United States, and

pursuant to Integra's own Code of Conduct;

(ii) Conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(iii) Remain informed as to how Integra conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(iv) Establish and maintain systematic and accurate records and reports of the business and internal affairs of Integra and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(v) Maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Integra's operations would comply with all applicable laws and Integra's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;

(vi) Exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;

(vii) Refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(viii) Examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate

disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

52. Each of the Individual Defendants further owed to Integra and the shareholders the duty of loyalty requiring that each favor Integra's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence, or knowledge of the affairs of the Company to gain personal advantage.

53. At all times relevant hereto, the Individual Defendants were the agents of each other and of Integra and were at all times acting within the course and scope of such agency.

54. Because of their advisory, executive, managerial, and directorial positions with Integra, each of the Individual Defendants had access to adverse, non-public information about the Company.

55. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Integra.

INTEGRA'S CODE OF CONDUCT

56. The Company's Code of Conduct begins with a letter from Defendant De Witte, which states, in relevant part:

Our Code of Conduct is the foundation for how we behave at Integra and ensures that we conduct business to the highest standards of ethics and integrity. Just as we do what's right for our customers and partners, we should always do the right thing with the confidence to make good decisions—by understanding and following the Code. It distills our values and policies and is aligned with industry and government standards.

57. The Code of Conduct states that it applies to "all employees, including officers and directors" and that the Company "expect[s] contractors, suppliers, and other third parties working on behalf of Integra to meet the standards of ethics and compliance set out in this Code."

58. Under a section titled “We Comply With Applicable Laws and Regulations,” Integra’s Code of Conduct states, in relevant part:

As a publicly traded global corporation in the healthcare industry, Integra is subject to numerous laws and regulations. Our reputation, integrity, and trustworthiness depend on remaining in compliance with these laws and regulations. Our rigorous compliance program ensures that we achieve this goal (see Our Global Compliance Program)

In our pursuit of excellence, we comply with all applicable laws, regardless of whether they are discussed in this Code or Integra policy documents.

59. Under the section titled “Our Global Compliance Program,” the Code of Conduct states, in relevant part:

We are committed to compliance with national, state, and local laws, rules, and our own policies and procedures. If you have questions or concerns, we encourage you to discuss them with your supervisor or department head. Integra may modify, monitor, and audit this Code of Conduct from time to time. At Integra, we cooperate with audits and investigations, whether internal or external. To that end, we shall not make any false or misleading statements in connection with an audit or investigation. We will not take any other action that could interfere or improperly influence an audit, inspection, or investigation.

Chief Compliance Officer

This officer oversees compliance with all applicable laws, this Code, and all related Integra policies and procedures. The Chief Compliance Officer directs the Global Compliance Program and reports to the Executive Vice President, Chief Legal Officer, and Secretary. . . .

Compliance Committee

This committee is made up of corporate officers. Its purpose is to implement and maintain the Global Compliance Program.

60. Under a section titled “We Deliver Safe and High-Quality Products,” the Code of Conduct states:

What We Stand For

What we do matters. This is especially true when it comes to the safety and quality of our products. We never compromise when it comes to regulatory compliance,

and we strive to provide the highest quality products to our customers.

Why It Matters

Our commitment to quality is central to how we operate. Surgeons rely on our products in their daily work with patients. We must keep quality and safety at the core of what we do. In the end, patients rely on it.

How We Do the Right Thing

To ensure we deliver safe, high-quality products, we:

- Always follow all quality procedures and policies
- Never bypass quality controls
- Promote safety and quality in all places we make our products
- Report any quality or safety issues immediately
- Communicate with customers to replace worn or damaged products

WE MAKE PRODUCTS THAT ARE USED TO SAVE LIVES

Quality is at the core of what we do. Our Quality Department stands on these four principles:

- We provide life-saving products that are safe and effective.
- We are committed to continuous improvement. This applies to our Quality Management System, our products, and our services.
- We meet all regulatory requirements.
- We strive to meet the needs of our customers and partners. Our goal is total customer satisfaction.

WHAT ARE BEST PRACTICES FOR ENSURING QUALITY?

We must treat our products as if they will be used to treat our own friends and families. Many laws and regulations govern our products. We must be familiar with these in relation to our roles as part of the Integra team. Here are some key areas of compliance:

- Good manufacturing practices (GMPs)
- Quality system regulations (QSRs)
- Good laboratory practices (GLPs)
- Good tissue practices (GTPs)
- Guidelines for clinical studies

61. In a section titled “We Ensure Our Suppliers Uphold Our High Standards,” the

Code of Conduct states:

What We Stand For

We do what's right. This means our suppliers must adhere to standards as high as our own. Our partners help us create value, and they must share our integrity.

Why It Matters

We count on our partners to help us deliver life-saving products. Our values of integrity and excellence must flow through our supply chain. We can be held accountable for suppliers that break laws. We must choose our suppliers carefully and center quality in our processes. Our customers rely on it.

How We Do the Right Thing

To ensure that our suppliers uphold our high standards, we:

- Choose suppliers with an open and fair process based on business needs and qualifications
- Share our values with our suppliers and what we expect of them
- Report any concerns about supplier behavior to the Chief Compliance Officer
- Never work with a supplier we have not approved internally
- Communicate openly and honestly with suppliers to address concerns

62. In a section titled "We Avoid Conflicts of Interest," the Code of Conduct states, in relevant part:

What We Stand For

Our people are our strength, and we work together as a team. We never allow conflicts of interest to affect our judgment. We avoid even the appearance of such conflicts.

Why It Matters

As a team, we put the company first. This means making business decisions that are in the best interests of the company. Conflicts of interest, which put self-interest ahead of company interests, should never be tolerated. Our reputation for integrity depends on it.

How We Do the Right Thing

We avoid conflicts of interest when we:

- Never allow our personal relationships to affect our judgment

- Share with the Law Department any conflict of interest we think we may have
- Never use company information for personal gain
- Remove ourselves from conflict-of-interest decision-making processes that involve us
- Never represent the company in a dealing where we have a personal stake.
- ...

63. Under a section title “We Do Not Engage in Insider Trading,” the Code of Conduct states, in relevant part:

What We Stand For

We never use or share material, nonpublic information for the purposes of insider trading. Our integrity demands that we never seek personal gain this way.

Why It Matters

Insider trading is a serious violation that comes with serious penalties. These can include loss of employment, fines, and even jail time. Insider trading is unfair and distorts markets. It can also do serious harm to our reputation. We cannot lose the trust of our customers and their patients.

How We Do the Right Thing

To ensure we do not engage in insider trading, we:

- Keep inside information from being released or shared
- Share inside information with co-workers on a need-to-know basis only
- Never buy Integra shares or any other shares on the basis of inside information
- Never engage in “tipping,” or sharing inside information with others so they can profit from it
- Never spread false information to manipulate share prices

64. Under a section titled “We Keep Accurate Accounts and Records,” the Code of Conduct states:

What We Stand For

We need confidence to make good decisions and drive action. Keeping accurate accounts and records gives us that confidence. It is also the right thing to do.

Why It Matters

Integra is a publicly traded company. We therefore have an obligation to our shareholders to accurately present our financial information as regulated by the Securities and Exchange Commission (SEC). We also communicate with the public through press releases and presentations. Accurate records in such communications help us maintain trust with our partners and customers. They also support our decisiveness in executing business transactions.

How We Do the Right Thing

To keep accurate accounts and records, we:

- Comply with generally accepted accounting principles, our own controls, and all relevant laws and regulations
- Maintain books, expense reports, and receipts that honestly reflect financial transactions
- Never mislead or exaggerate about our finances
- Record all business transactions completely, accurately, in the proper period, and in a timely manner
- Submit all records to internal and external auditors in a timely manner

INTEGRA'S AUDIT COMMITTEE CHARTER

65. Integra's Audit Committee Charter states that the purpose of the Audit Committee is to oversee:

(i) the accounting and financial reporting processes of the Company and the audits of the financial statements of the Company; (ii) the independence, quality control and work of the Company's external independent auditor and the appointment and performance evaluation of the internal auditor (as defined below); and (iii) the Company's compliance program, including but not limited to the Company's compliance with the Foreign Corrupt Practices Act, False Claims Act, Physician Self-Referral Law (Stark) and Anti-Kickback Statute, and similar foreign requirements..

66. In a section titled "Duties and Responsibilities," the Audit Committee Charter states that the Audit Committee has the following duties and responsibilities, among others:

Interaction with the Independent Auditors

1. Appointment and Oversight.

(i) The Committee shall be directly responsible for the appointment and replacement, compensation, retention and

oversight of the work of the independent auditors (including resolution of any disagreements between Company management and the independent auditors regarding financial reporting) for the purpose of preparing or issuing an audit report or related work or performing other audit, review or attest services for the Company, and the independent auditors shall report directly to the Committee.

- (ii) The Committee shall be directly responsible for the appointment, compensation, retention and oversight of the work of any other registered public accounting firm engaged for the purpose of preparing or issuing an audit report or to perform audit, review or attestation services, which firm shall also report directly to the Committee. . . .

Annual Financial Statements and Annual Audit

- 4. Meetings with Management and the Independent Auditors. The Committee shall meet with management, the independent auditors and, if appropriate, the internal auditor, in connection with each annual audit to discuss the scope of the audit, the procedures to be followed and the staffing of the audit.
 - (i) The Committee shall review and discuss with management and the independent auditors any material off-balance sheet transactions, arrangements, obligations (including contingent obligations) and other relationships of the Company with unconsolidated entities of which the Committee is made aware that do not appear on the financial statements of the Company and that may have a material current or future effect on the Company's financial condition, results of operations, liquidity, capital expenditures, capital resources or significant components of revenues or expenses.
 - (ii) The Committee shall advise management, the internal auditor and the independent auditors that they are expected to provide to the Committee a timely analysis of significant issues and practices relating to accounting principles and policies, financial reporting and internal control over financial reporting.
- 5. Separate Meetings with the Independent Auditors.
 - (i) The Committee shall discuss with the independent auditors any significant issues arising from the most recent PCAOB

inspection of the independent auditors to the extent relevant to the Company, including the independent auditors' response to any identified accounting deficiencies.

- (ii) The Committee shall consider any reports or communications (and management's and/or the internal auditor's responses thereto) submitted to the Committee by the independent auditors required by or referred to in applicable PCAOB or other applicable standards, including, as applicable, reports and communications related to any illegal acts committed by management, and any other matters arising out of the audit that are significant to the oversight of the Company's financial reporting process, including complaints or concerns regarding accounting or auditing matters, that came to their attention during the course of the audit.
- (iii) The Committee shall obtain from the independent auditors in connection with any audit a timely report relating to the Company's annual audited financial statements describing: (A) all accounting policies and practices used that the independent auditors identify as critical; (B) all alternative treatments within GAAP for policies and practices related to material items that have been discussed among management and the independent auditors, including the ramifications of the use of such alternative disclosures and treatments, and the treatment preferred by the independent auditors; (C) all other material written communications between the independent auditors and management of the Company, such as any management letter, management representation letter, reports on observations and recommendations on internal controls, independent auditors' engagement letter, independent auditors' independence letter, schedule of unadjusted audit differences and a listing of adjustments and reclassifications not recorded, if any; and (D) assurances that the audit was conducted in a manner consistent with Section 10A of the Exchange Act, which sets forth certain procedures to be followed in any audit of financial statements required under the Exchange Act.

- 6. Recommendation to Include Financial Statements in Annual Report. The Committee shall, based on the review and discussions in paragraphs 4 and 5 above, and based on the disclosures received from the independent auditors regarding its independence and discussions with the auditor regarding such independence pursuant to subparagraph 3(ii) above, determine whether to recommend to the

Board that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year subject to the audit.

Internal Audit

7. Appointment. The Committee shall review and approve the appointment and replacement of the internal auditor director and oversee the evaluation of his or her performance and determinations of his or her compensation.
8. Communications with the Internal Auditor. The Committee shall receive communications from the internal audit director on internal audit's performance relative to its annual audit plan and other matters.
9. Internal Audit Charter. The Committee shall at least annually review and reassess the Internal Audit Charter and submit any recommended changes to the Board for its consideration.
10. Internal Audit Plan. The Committee shall review and approve the annual risk based internal audit plan and significant changes to that plan.
11. Internal Audit Budget. The Committee shall review and approve the internal audit budget and resources necessary to achieve annual audit plan objectives.
12. Inquiries. The Committee shall make appropriate inquiries of management and the internal audit director to determine whether there are inappropriate scopes or resource limitations.
13. Quality Assessments. The Committee shall review the results of the internal and external quality assessments.

Other Duties and Responsibilities

14. The Committee shall review all related party transactions on an ongoing basis, and all such transactions must be approved by the Committee in accordance with the policies of the Company in effect from time to time.
15. Receive a report, at least annually, from management regarding, and review compliance processes relating to, the Company's Code of Conduct, including the Company's compliance with the Foreign Corrupt Practices Act, False Claims Act, Physician Self-Referral

Law (Stark) and Anti-Kickback Statute, and similar foreign requirements, and to review and oversee the Company's policies, procedures and programs designed to promote and monitor compliance.

16. Meet in executive session with the Chief Compliance Officer the Chief Legal Office or others members of senior management, at his, her, or the Committee's request, to discuss any aspect of the performance of the Company's compliance program, including the results of significant compliance audits and investigations conducted within the compliance program and corrective or preventive actions taken as a result of significant compliance audits and investigations, the processes and procedures for management's monitoring of compliance with laws, and major legislative and regulatory developments that may have a significant impact on the Company.
17. The Committee shall discuss with management and/or the independent auditors, as appropriate, (i) legal matters that may have a material impact on the financial statements, (ii) any fraud involving management or other employees who have a significant role in the Company's internal controls, (iii) compliance policies, and (iv) any correspondence from or with regulators or governmental agencies, any employee complaints or any published reports that raise material issues regarding the Company's financial statements, financial reporting process, accounting policies, internal audit function or compliance policies.
18. The Committee shall discuss with the Company's Chief Legal Officer, Chief Compliance Officer or outside counsel any legal matters brought to the Committee's attention that could reasonably be expected to (i) have a material impact on the Company's financial statements or (ii) result in a material violation of the Company's compliance policies, including the results and effectiveness of management's investigation and follow-up (including disciplinary action) of any instances of material non-compliance with the Company's compliance policies.
19. Advise the Board with respect to the Company's compliance program, including but not limited to the Company's compliance with the Foreign Corrupt Practices Act, False Claims Act, Physician Self-Referral Law (Stark) and Anti-Kickback Statute, and similar foreign requirements.
20. The Committee shall request assurances from management, and the Company's internal auditors that the Company's foreign subsidiaries

and foreign affiliated entities, if any, are in conformity with applicable legal requirements, including disclosure of affiliated party transactions.

21. The Committee shall review and discuss any reports concerning material violations submitted to it by any attorney employed by or performing legal services for the Company pursuant to the SEC attorney professional responsibility rules (17 C.F.R. Part 205), or otherwise.
22. The Committee shall review and approve procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters. The Committee shall also review and approve procedures for the confidential and anonymous submission by employees regarding questionable accounting or auditing matters.
23. The Committee shall prepare any report or other disclosures, including any recommendation of the Committee, required by the rules of the SEC to be included in the Company's annual proxy statement.
24. The Committee, through its Chair, shall report regularly to, and review with, the Board any issues that arise with respect to the quality or integrity of the Company's financial statements, the Company's compliance with legal or regulatory requirements, the performance and independence of the Company's independent auditors, the performance of the Company's internal audit function, the effectiveness of the Company's compliance policies or any other matter the Committee determines is necessary or advisable to report to the Board.
25. The Committee shall oversee the quality and integrity of the Company's data relating to climate change and similar environmental, social and governance matters included in the Company's filings with the SEC, including such compensation metrics included in the Company's annual proxy statement and any greenhouse gas disclosures required by any applicable law, rule or regulation.
26. The Committee shall at least annually review and reassess the Treasury Department's policies and submit any recommended changes to the Board for its consideration.
27. The Committee shall at least annually prepare and review with the Board an evaluation of the performance of the Committee and its

members, including a review of the Committee's compliance with this Charter.

28. The Committee shall at least annually review and reassess this Charter and submit any recommended changes to the Board for its consideration.
29. The Committee shall perform such other activities and make such other recommendations to the full Board on such matters, within the scope of its functions and consistent with this Charter, as may come to its attention, including any issues regarding the integrity of financial statements, the Company's compliance program, performance of the independent auditors, and performance of internal audit functions, and as the Committee may deem necessary or appropriate.

SUBSTANTIVE ALLEGATIONS

The Company's Background

67. Founded in 1989, Integra is a leading global medical technology company that develops and manufactures numerous product lines, including an engineered collagen technology platform used to repair and regenerate tissue, surgical instruments, neurosurgical products, and advanced wound care.

68. The Company's products are sold in more than 130 countries through a direct sales force as well as distributors and wholesalers. Integra manufactures and sells medical technologies and products in two reportable business segments: Codman Specialty Surgical and Tissue Technologies. The Company's Tissue Technology segment focuses on complex wound surgery, surgical reconstruction, and peripheral nerve repair and consists of five unique regenerative technology areas.

69. The Company's most lucrative portfolio of products are its regenerative surgical tissue products, also known as "biologic mesh."

70. In July 2015, Integra acquired TEI Biosciences Inc. and TEI Medical Inc. ("TEI") in order to expand the Company's surgery and reconstructive wound care product offering (the

“Acquisition”). At the time of the Acquisition, TEI was an emerging producer of biologic mesh products, including SurgiMend and PriMatrix. Both SurgiMend and PriMatrix are EBM products.

71. Through the Acquisition, Integra acquired the ability to produce SurgiMend and PriMatrix and assumed the lease of the Boston Facility, which was the exclusive manufacturing center for SurgiMend and PriMatrix.

72. After the Acquisition, Integra increasingly focused on its biologic mesh portfolio, including SurgiMend and PriMatrix, and assured investors that its focus on biologic mesh devices was integral to the Company’s growth.

Applicable FDA Regulations

73. Integra, as a manufacturer of medical technology, is required to comply with all FDA regulations governing the manufacture of medical devices, including cGMP.

74. Manufacturers of medical devices are required to comply with cGMP regulations, which are minimum requirements set by the FDA for the methods, facilities, and controls used in the design, manufacturing, packaging, labeling, storage, installation, and servicing of medical devices. *See 21 C.F.R. § 820.1(a)(1).*

75. Furthermore, medical devices are subject to the “adulteration provisions” of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”). *See 21 U.S.C. § 351.* Under these regulations, a device is “deemed to be adulterated” if a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under [cGMP].” *21 U.S.C. § 351(h).*²

76. Accordingly, any medical device that is not manufactured in accordance with

² 21 U.S.C. § 351(h) directs you to the requirements set forth in 21 U.S.C. § 360j(f)(2), which have been codified into 21 C.F.R. § 820.1(a)(1), the cGMP regulations.

cGMP is deemed “adulterated” by the FDA.

77. The cGMP standards require medical device manufacturers, among other things, to establish strong quality management systems, maintain sufficient personnel, establish and maintain procedures to control the design of devices, validate all testing procedures, control environment conditions, prevent contamination, and detect and correct any and all quality deviations. 21 C.F.R. Pt. 820, *et seq.*

78. A key part of cGMP is that medical device manufacturers must develop a “Correct and Preventative Action” (“CAPA”) system, which is a quality management system designed for implementing corrective and preventative actions after defects in the manufacturing process have been identified. 21 C.F.R. § 820.100.

79. The FDA places a special emphasis on data integrity in accordance with cGMP to ensure that all testing and quality control data by manufacturers is complete, consistent, accurate, and free from potential manipulation. The FDA has explained that “[d]ata integrity is critical throughout the CGMP data life cycle, including in the creation, modification, processing, maintenance, archival, retrieval, transmission, and disposition of data after the record’s retention period ends. System design and controls should enable easy detection of errors, omissions, and aberrant results throughout the data’s life cycle.”³

80. To ensure compliance with cGMP, the FDA conducts periodic inspections of medical device manufacturing facilities.⁴ If, during their inspection, investigators observe any

³ U.S. Food and Drug Administration, *Data Integrity and Compliance with Drug CGMP*, chrome-extension://efaidnbmnnibpcajpcglclefindmkaj/https://www.fda.gov/media/119267/download (last visited Feb. 19, 2025).

⁴ U.S. Food and Drug Administration, *Inspection Classification Database*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database (last visited Feb. 19, 2025).

objectionable conditions that may constitute violations of the FD&C Act, including violations of cGMP, the FDA will issue a Form 483 to the manufacturer.⁵ The Form 483 is then discussed with the manufacturer's management at the conclusion of the inspection and each observation is read and discussed so there is a full understanding of what the observations are and what they mean. *Id.* The FDA will also prepare an Establishment Inspection Report ("EIR") in connection with the inspection, which includes more details on its observations. *Id.* Inspected manufacturers are encouraged to respond to Form 483s in writing within fifteen days from its issuance.⁶

81. In cases where the FDA believes that the manufacturer has failed to take adequate corrective and preventative measures in response to a Form 483, the FDA may also issue a warning letter to the manufacturer. Warning letters identify concerns observed by the FDA, such as poor manufacturing practices, problems with claims for what a product can do, or incorrect directions for use, and provide an opportunity for the manufacturer to address the FDA's concerns within a certain timeframe.⁷

82. Manufacturers that violate cGMP requirements face severe sanctions from the FDA. For instance, among other things, the FDA has the authority to impose civil money penalties on manufacturers or remove a product from the market if it finds that the manufacturer is in violation of cGMP regulations. *See* 21 U.S.C. § 333; 21 C.F.R. §800.55(i).

cGMP Issues at Integra and its Subsidiaries

⁵ U.S. Food and Drug Administration, *FDA Form 483 Frequently Asked Questions*, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions> (last visited Nov. 25, 2024).

⁶ *Inspection Classification Database*, *supra* note 4.

⁷ U.S. Food and Drug Administration, *About Warning and Close-Out Letters*, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters> (last visited Feb. 19, 2025).

83. In October and November 2018, the FDA conducted an inspection of the Boston Facility, where investigators discovered numerous cGMP violations, including violations of the requirements for preventing toxic bacterial contamination of the Company's surgical tissue reconstruction products. In connection with this inspection, on November 2, 2018, the FDA issued a Form 483 to Integra and TEI (the "2018 Form 483") and held a "close-out" meeting with members of Integra's management to discuss the findings. On November 28, 2018, the FDA issued an EIR related to the same inspection (the "2018 EIR"). The 2018 Form 483 and 2018 EIR cited Integra and TEI for a number of deficiencies in its contamination controls, environmental controls, process validation controls, and CAPA controls related to the Company's manufacturing of EBM products. Additionally, the 2018 EIR stated that the FDA was directed to send all correspondence related to this inspection directly to Defendant Arduini.

84. Integra and TEI responded to the 2018 Form 483 and 2018 EIR on November 27, 2018, December 27, 2018, January 31, 2019, and February 28, 2019.

85. Then, on March 6, 2019, just before the start of the Relevant Period, the FDA issued TEI an official Warning Letter, which was addressed to Defendant Arduini (the "2019 Warning Letter"). The 2019 Warning Letter was later published on the FDA's website. The 2019 Warning Letter repeated the deficiencies detailed in the 2018 Form 483 and the 2018 EIR.

86. Specifically, the 2019 Warning Letter stated that Integra and TEI were not taking sufficient action to correct the cGMP violations identified by the FDA. The 2019 Warning Letter stated, in relevant part:

We reviewed your firm's response to FDA 483 observations 1-3 (Warning Letter cite 1 and 2 above) and conclude they are not adequate to address the above violations. We acknowledge that after the inspection, your (b)(4) of all products, so you can test individual lots for endotoxin. We also understand that you opened additional CAPA's to address FDA's above findings and are in the process of implementing a number of corrective actions to address these items. **However, the**

above deficiencies observed during our inspection are significant and demonstrate a systemic failure of your firm's quality systems.

(Emphasis added).

87. The Company disclosed the 2019 Warning Letter to investors on March 11, 2019. However, as detailed herein, the Individual Defendants consistently downplayed the systemic cGMP violations documented by the FDA and assured investors that the Company was effectively remediating the violations.

88. In October and November of 2021, the FDA conducted a nine-day inspection of the Boston Facility. At the conclusion of the inspection, on November 12, 2021, the FDA issued a Form 483 to TEI and Integra (the “2021 Form 483”). The 2021 Form 483 cited Integra for cGMP deficiencies in its environmental controls and process validation controls that the Company failed to remediate after the 2018 Form 483. As detailed herein, the Company disclosed the 2021 Form 483 to investors on February 24, 2022, nearly four months after the issuance of the 2021 Form 483. Again, in its announcement and afterwards, Integra downplayed the systemic violations of cGMP and assured investors that the Company was actively remediating the violations.

89. In October 2022, the Company was again informed that the Boston Facility was in violation of numerous cGMP regulations when an internal whistleblower reported the cGMP violations to the Company’s Compliance Department. This whistleblower warned the Company that thirty-seven lots of unfinished products awaiting distribution at the Boston Facility were exposed to bacterial endotoxin contamination. However, Integra failed to properly investigate and address this purported violation.

90. On March 1, 2023, in response to the whistleblower’s complaint, the FDA commenced a *ten-week* inspection of the Boston Facility and issued yet another Form 483 to TEI and Integra on May 17, 2023 (the “2023 Form 483”). The 2023 Form 483 detailed the systemic

violations of cGMP at the Boston Facility, including deficiencies in the Company’s contamination and process validation controls, product non-conformance controls, and CAPA controls.

91. On March 13, 2023, twelve days into the FDA’s inspection of the Boston Facility, the Company placed the production and distribution of all products manufactured at the Boston Facility on hold.

92. Then, on May 23, 2023, after consultation with the FDA, the Company filed a Form 8-K with the SEC wherein it announced that it initiated a voluntary recall of products manufactured in the Boston facility distributed between March 1, 2018 and May 22, 2023 (the “Recall”), including SurgiMend, PriMatrix, and other biologic mesh products, and extended the temporary halt of manufacturing at the facility to implement additional detection and quality controls. Integra explained that it “identified through an internal investigation process in its Boston facility deviations with endotoxin testing that may have resulted in the release of products with higher levels of endotoxins than permitted by the product specifications,” and that it “decided to initiate the voluntary recall and extend the temporary halt of manufacturing at its Boston facility to implement additional detection and quality controls.”

93. On June 8, 2023, Integra responded to the 2023 Form 483, admitting that there were “areas requiring additional attention and improvement” and acknowledging the need to “adjust [Integra’s] previously established remediation plans.” This letter was signed by Susan Krause, Integra’s Chief Quality Officer, and copied Defendant De Witte.

94. Then, on July 19, 2023, TEI received a Warning Letter, dated July 17, 2023, from the FDA related to quality system issues at the Boston Facility (the “2023 Warning Letter”). The 2023 Warning Letter was later publicly published on the FDA’s website. The 2023 Warning Letter, which was addressed to Defendant De Witte, reprimanded Integra for the Boston Facility’s

systemic, pervasive, and never-remediated cGMP violations. The 2023 Warning Letter stated that Integra still had not “identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming product[s]” and noted that many of the deficiencies identified during the FDA’s 2023 investigation were repeat “deficienc[ies] from [the FDA’s] 2019 Warning Letter to this facility.” Consequently, the FDA concluded the Boston Facility’s products were “adulterated.”

95. The 2023 Warning Letter concluded, that although Integra had instituted the Recall, the remediation efforts by the Company were “not adequate” and that self-regulation by the Company was no longer an option. The 2023 Warning Letter informed the Company that it must obtain a “certification by an outside expert consultant that he/she has conducted an audit of your establishment’s manufacturing and quality assurance systems relative to [cGMP] requirements,” submit the consultant’s report to the FDA, and also submit a “certification by your establishment’s Chief Executive Officer [] that he or she has received the consultant’s report and that your establishment has initiated or completed all corrections called for in the report” to the FDA.

96. Despite the continuous investigations by the FDA and the FDA’s findings of systemic cGMP violations, the Individual Defendants downplayed the severity of these finding and investigations to investors.

Individual Defendants’ Materially False and Misleading Statements

97. Throughout the Relevant Period, the Individual Defendants made materially false and misleading statements related to the Company’s compliance with cGMP regulations. Specifically, the Individual Defendants assured investors that the Company was compliant with cGMP in its manufacturing of its biologic mesh products, that it was taking steps to remediate the

deficiencies found by the FDA at the Boston Facility, and that the FDA's findings would not impact the Company's business or financial prospects.

98. For instance, on the first day of the Relevant Period, March 11, 2019, the Company filed a Form 8-K with the SEC to disclose the 2019 Warning Letter to investors. In the Form 8-K, Integra assured investors that the Company was taking meaningful actions to remediate the issues identified in the 2019 Warning Letter, stating, in relevant part:

The warning letter relates to quality systems issues at our manufacturing facility located in Boston, Massachusetts. The letter resulted from an inspection held at that facility in October and November 2018, and did not identify any new observations that were not already provided in the Form 483 that followed the inspection. ***We take the matters identified in the letter seriously and are in the process of preparing a written response to the letter.*** The Company has provided detailed responses to the FDA as to its corrective actions on a monthly basis and, since the conclusion of the inspection, ***has undertaken significant efforts to remediate the observations and continues to do so.***

The warning letter does not restrict the Company's ability to manufacture or ship products or require the recall of any products. . . .

The Company does not expect to incur material incremental expense for remediation activities.

(Emphasis added).

99. On April 16, 2019, the Company filed its annual proxy statement on a Schedule 14A with the SEC (the "2019 Proxy"). The 2019 Proxy, in a section titled "The Board's Role in Risk Oversight," assured investors that the Board had effective risk oversight mechanisms in place, stating, in relevant part:

The Board of Directors has overall responsibility for the oversight of risk management at the Company. . . .

Each year management presents a detailed report to the Board on the Company's processes in place for assessing and addressing risks, providing periodic reports on compliance regimens and reporting material information to the Board. This report assists the Board in its evaluation of the Company's risk management practices.

Our President and Chief Executive Officer, who functions as our chief risk officer, has responsibility for ensuring that management provides periodic updates to the Board or Board Committees regarding risks in many areas, among them accounting, treasury, information systems, legal, governance, legislative (including reimbursement), general compliance (including sales and marketing compliance), quality, **regulatory**, climate-related risks and opportunities, corporate development, operations and sales and marketing. Both formal reports and less formal communications derive from a continual flow of communication throughout the Company regarding risk and compliance. ***We believe that our Board and senior management team promote a culture that actively identifies and manages risk, including effective communication throughout the entire organization and to the Board and Committees.***

(Emphasis added).

100. On April 29, 2019, the Company filed its quarterly report for the period ended March 31, 2019 on a Form 10-Q with the SEC (the “1Q19 10-Q”). In the 1Q19 10-Q, Integra continued to mislead investors by assuring them that remediation efforts at the Boston Facility were underway, and that the effects of the 2019 Warning Letter would not have a significant effect on the Company, stating, in relevant part:

The Company has provided detailed responses to the FDA as to its corrective actions on a monthly basis and, since the conclusion of the inspection, ***has undertaken significant efforts to remediate the observations and continues to do so.*** The warning letter does not restrict the Company’s ability to manufacture or ship products or require the recall of any products. . . .

The Company does not expect to incur material incremental expense for remediation activities.

(Emphasis added).

101. The 1Q19 10-Q was signed by Defendants Arduini, Coleman, and Mosebrook. The 1Q19 10-Q was also accompanied by certifications made by Defendants Arduini and Coleman pursuant to Exchange Act Sections 13a-15(e) and 15d-15(e) and Section 302 of the Sarbanes-Oxley Act of 2002 (the “SOX Certifications”). In the SOX Certifications, Defendants Arduini and Coleman attested to the accuracy of the 1Q19 10-Q.

102. On July 25, 2019, the Company filed its quarterly report for the period ended June 30, 2019 on a Form 10-Q with the SEC (the “2Q19 10-Q”). The 2Q19 10-Q contained the same materially false and misleading statements regarding the remediation efforts at the Boston Facility the effects of the 2019 Warning Letter on the Company as the 1Q19 10-Q. *See ¶ 100.*

103. The 2Q19 10-Q was signed by Defendants Arduini, Anderson, and Mosebrook. The 2Q19 10-Q was also accompanied by SOX Certifications signed by Defendants Arduini and Coleman, wherein they attested to the accuracy of the 2Q19 10-Q.

104. On November 25, 2019, the Company filed its quarterly report for the period ended September 30, 2019 on a Form 10-Q with the SEC (the “3Q19 10-Q”). The 3Q19 10-Q contained the same materially false and misleading statements regarding the remediation efforts at the Boston Facility the effects of the 2019 Warning Letter on the Company as the 1Q19 10-Q. *See ¶ 100.*

105. The 3Q19 10-Q was signed by Defendants Arduini, Anderson, and Mosebrook. The 3Q19 10-Q was also accompanied by SOX Certifications signed by Defendants Arduini and Anderson, wherein they attested to the accuracy of the 3Q19 10-Q.

106. On February 19, 2020, the Company hosted an earnings call for investors and analysts to discuss its financial results for the fourth quarter of 2019 (the “4Q19 Earnings Call”). During the 4Q19 Earnings Call, Defendant Coleman assured investors that the remediation efforts at the Boston Facility were on track and would not have any lasting effects on the Company’s production. For instance, in response to a question on the Company’s percentage of sales from regenerative products, Defendant Coleman stated, in relevant part, “Boston, we’ve been supply constrained for a different reason. You probably remember, we went through an FDA audit. ***We've been doing quality remediation efforts throughout 2019. There are no patient safety issues here.***” (Emphasis added).

107. Also during the 4Q19 Earnings Call, in response to a question regarding the remediation efforts of the Company, Defendant Coleman stated, in relevant part, “[w]e’re on a better path forward in terms of supply out of Boston. And ***we expect to have the remediation efforts complete in the short-term*** and then get the warning letter lifted in 2020.” (Emphasis added).

108. Furthermore, Defendant Coleman assured investors during the 4Q19 Earnings Call that the FDA’s inspection and findings would not have an impact on the Company’s ability to manufacture EBM products at the Boston Facility, stating, in relevant part:

We are continuing to ship out of [the Boston Facility], but there were changes we had to make to the actual physical facility and those changes required us to actually shut down the plant, which is planned at the end of the third quarter and into the fourth quarter. . . .

As we are going through plant shutdown, we extended that shut down for several weeks to add an additional production line, which is going to get us 50% more capacity as we enter 2020. . . .

(Emphasis added).

109. On February 21, 2020, the Company filed its annual report for 2019 on a Form 10-K with the SEC (the “2019 10-K”). The 2019 10-K assured investors that the remediation efforts at the Boston Facility were underway and would not have a significant effect on Integra, stating, in relevant part:

The Company has provided detailed responses to the FDA as to its corrective actions on a monthly basis and, since the conclusion of the inspection, ***has undertaken significant efforts to remediate the observations and continues to do so. The warning letter does not restrict the Company’s ability to manufacture or ship products or require the recall of any products.*** Nor does it restrict our ability to seek FDA 510(k) clearance of products. . . .

The company does not expect to incur material incremental expense for remediation activities.

(Emphasis added).

110. The 2019 10-K was signed by Defendants Arduini, Anderson, Mosebrook, Essig, Ballintyn, Bradley, Hill, Howell, Morel, Murphy, and Schade. The 2019 10-K was also accompanied by SOX Certifications made by Defendants Arduini and Anderson, wherein they attested to the accuracy of the 2019 10-K.

111. On April 8, 2020, the Company filed its annual proxy statement on a Schedule 14A with the SEC (the “2020 Proxy”). The 2020 Proxy contained the same materially false and misleading statements as the 2019 Proxy regarding the Company’s risk oversight, stating, in relevant part:

In general, the Board of Directors has overall responsibility for the oversight of risk management at the Company. . . .

Each year management presents a detailed report to the Board on the Company’s processes in place for assessing and addressing risks, providing periodic reports on compliance regimens and reporting material information to the Board. This report assists the Board in its evaluation of the Company’s risk management practices.

Our President and Chief Executive Officer, who functions as our chief risk officer, has responsibility for ensuring that management provides periodic updates to the Board or Board Committees regarding risks in many areas, among them accounting, treasury, information systems, legal, governance, legislative (including reimbursement), general compliance (including sales and marketing compliance), quality, regulatory, environment, social and governance (ESG) risks and opportunities, corporate development, operations and sales and marketing. Both formal reports and less formal communications derive from a continual flow of communication throughout the Company regarding risk and compliance. ***We believe that our Board and senior management team promote a culture that actively identifies and manages risk, including effective communication throughout the entire organization and to the Board and Board Committees.***

(Emphasis added).

112. On May 7, 2020, the Company held an earnings call for investors and analysts to discuss its financial results for the first quarter of 2020 (the “1Q20 Earnings Call”). During the 1Q20 Earnings Call, Defendant Anderson assured investors that the Company had a continued

demand for its biologic mesh products, stating in relevant part, “[s]ales of [] SurgiMend increased double digits in the quarter, driven by the increase in supply coming from the capital investments we initiated last year at [the Boston Facility].” Defendant Coleman also made statements about the Company’s growth from the Boston Facility and biologic mesh products, stating, in relevant part:

So we have about 17 manufacturing sites, not all as equal each of the sites, to Carrie's point. And certain plants like Boston and Memphis, which are regenerative plants we make in and out of tissue in Memphis. SurgiMend used for hernia as well as in plastic reconstructive along with PriMatrix for wound care in Boston. ***Those plants are pretty much running normal capacity. And during this period of lower demand, we're actually building safety stock.*** These are going to be products that we should see very good growth when things come back to normal, when we get the regular procedures. ***So double-digit growth we were posting last year. We continue to expect that. Once we get back to normal, we're going to have plenty of safety stock to support that ramp when it comes back.*** So that's the good news.

(Emphasis added).

113. Also on May 7, 2020, the Company filed its quarterly report for the period ended March 31, 2020 on a Form 10-Q with the SEC (the “1Q20 10-Q”). The 1Q20 10-Q contained substantially the same materially false and misleading statements regarding the remediation efforts at the Boston Facility and the effects of the 2019 Warning Letter on the Company as the 1Q19 10-Q. *See ¶ 100.*

114. The 1Q20 10-Q was signed by Defendants Arduini, Anderson, and Mosebrook. The 1Q20 10-Q was also accompanied by SOX Certifications made by Defendants Arduini and Anderson, wherein they attested to the accuracy of the 1Q20 10-Q.

115. On May 20, 2020, Defendant Anderson attended the UBS Global Virtual Healthcare Conference on behalf of Integra. In response to an analyst question at the conference regarding “the factors driving the wound business” and the Company’s manufacturing, Defendant Anderson assured the analyst that the Boston Facility was in good shape, stating, in relevant part, “in terms of the Boston facility, that’s the one that really is untouched from an overall

manufacturing plan perspective. We're continuing to run that factory as before in order for us to use this time to build up safety stock in SurgiMend and PriMatrix."

116. On August 10, 2020, the Company filed its quarterly report for the period ended June 30, 2020 on a Form 10-Q with the SEC (the "2Q20 10-Q"). The 2Q20 10-Q contained substantially the same materially false and misleading statements regarding the remediation efforts at the Boston Facility and the effects of the 2019 Warning Letter on the Company as the 1Q19 10-Q. *See ¶ 100.*

117. The 2Q20 10-Q was signed by Defendants Arduini, Anderson, and Mosebrook. The 2Q20 10-Q was also accompanied by SOX Certifications made by Defendants Arduini and Anderson, wherein they attested to the accuracy of the 2Q20 10-Q.

118. On October 28, 2020, the Company hosted an earnings call for investors and analysts to discuss its financial results for the third quarter of 2020 (the "3Q20 Earnings Call"). During the 3Q20 Earnings Call, Defendant Coleman touted the Company's EBM products manufactured at the Boston Facility and highlighted how these products were critical to Integra's future growth, stating, in relevant part:

I think overall, *we're in great shape when you look at our regenerative supply. . .*

. . . And when I think about our Waston plan, which makes SurgiMend and PriMatrix, I think about Memphis and the amniotics business, we can actually now build more product, and *we've actually built more safety stock for those regenerative products. So we're in very good shape.* And as Carrie mentioned, as sales start to ramp up with our regenerative products. These are very high-margin products for us, 80% plus. So we're well positioned not just to capitalize on the top line, but also to show that favorable mix and actually drive higher gross margins going forward.

(Emphasis added).

119. On October 29, 2020, the Company filed its quarterly report for the period ended September 30, 2020 on a Form 10-Q with the SEC (the "3Q20 10-Q"). The 3Q20 10-Q contained

the same materially false and misleading statements regarding the remediation efforts at the Boston Facility and the effects of the 2019 Warning Letter on the Company as the 1Q19 10-Q. *See ¶ 100.*

120. The 3Q20 10-Q was signed by Defendants Arduini, Anderson, and Mosebrook. The 3Q20 10-Q was also accompanied by SOX Certifications made by Defendants Arduini and Anderson, wherein they attested to the accuracy of the 3Q20 10-Q.

121. On February 23, 2021, Integra filed its annual report for 2020 with the SEC on a Form 10-K (the “2020 10-K”). The 2020 10-K assured investors that the remediation efforts at the Boston Facility were underway and would not have a significant effect on Integra, stating, in relevant part:

The Company submitted its initial response to the FDA Warning Letter on March 28, 2019 and provides regular progress reports to the FDA as to its corrective actions and, since the conclusion of the inspection, ***has undertaken significant efforts to remediate the observations and continues to do so. The warning letter does not restrict the Company’s ability to manufacture or ship products or require the recall of any products. . . .***

The Company does not expect to incur material incremental expense for remediation activities.

(Emphasis added).

122. The 2020 10-K was signed by Defendants Arduini, Anderson, Mosebrook, Essig, Ballintyn, Bradley, Hill, Howell, Morel, Murphy, and Schade. The 2020 10-K was also accompanied by SOX Certifications made by Defendants Arduini and Anderson, wherein they attested to the accuracy of the 2020 10-K.

123. On April 9, 2021, the Company filed its annual proxy statement for 2021 on a Schedule 14A with the SEC (the “2021 Proxy”). Similar to the 2019 Proxy and the 2020 Proxy, the 2021 Proxy contained a section titled “The Board’s Role in Risk Oversight,” wherein it

described the Board's efforts in oversight of risk management. However, for the 2021 Proxy touted the Company's new "Enterprise Risk Management" program, stating, in relevant part:

The Board of Directors has overall responsibility for the oversight of risk management at the Company and has delegated responsibility for the oversight of certain areas of risk management to the Committees of the Board, as described below. . . .

The Company has also implemented an Enterprise Risk Management ("ERM") program to further enhance its oversight of risks inherent to the business. This ERM program allows the Board and management to gain a greater understanding and awareness of risks facing the business and to mitigate those risks.

In addition to periodic updates management provides to the Board on the ERM program, management presents an annual report to the Board detailing the Company's processes for (1) assessing and addressing risks, (2) **compliance reporting**, and (3) the reporting of other material information.

Our President and Chief Executive Officer, who functions as our chief risk officer, has responsibility for ensuring management provides periodic updates to the Board or Board committees regarding risks in many areas, among them accounting, treasury, information systems, legal, governance, legislative (including reimbursement), general compliance (including sales and marketing compliance), quality, **regulatory**, sustainability, environment, social and governance ("ESG") risks and opportunities, corporate development, operations and sales and marketing. Both formal reports and less formal communications between the Board and our President and Chief Executive Officer derive from a continual flow of communication throughout the Company regarding risk and compliance. **We believe our Board and senior management team promote a culture that actively identifies and manages risk.**

The ERM program, along with our annual processes for creating and reviewing with the Board our strategic plan, budget and internal audit plans, as well as regular processes and communications throughout the Company, including between management and the Board and Board committees, **combine to ensure the Company is continually addressing its business risks in a disciplined fashion.**

(Emphasis added).

124. The 2021 Proxy also highlighted the Company's Code of Conduct and its "comprehensive compliance program," stating, in relevant part, "Integra is committed to its Code of Conduct and to holding the Company accountable as a leader in the medical technology

industry. The Company operates a comprehensive compliance program, which is supported by a training program led by Integra’s Chief Compliance Officer.”

125. On April 29, 2021, Integra filed its quarterly report for the period ended March 31, 2021 on a Form 10-Q with the SEC (the “1Q21 10-Q”). The 1Q21 10-Q contained substantially the same materially false and misleading statements regarding the remediation efforts at the Boston Facility and the effects of the 2019 Warning Letter on the Company as the 1Q19 10-Q. See ¶ 100.

126. The 1Q21 10-Q was signed by Defendants Arduini, Anderson, and Mosebrook. The 1Q21 10-Q was also accompanied by SOX Certifications made by Defendants Arduini and Anderson, wherein they attested to the accuracy of the 1Q21 10-Q.

127. On May 20, 2021, the Company hosted its 2021 Virtual Investors Day. During the 2021 Virtual Investors Day, Defendant Coleman assured investors that remediation efforts at the Boston facility were “now complete” and again downplayed the effects of the FDA investigation, stating, in relevant part, “the key takeaway here is we’ve strengthened our quality operating mechanisms and reduced quality risk with enhanced rigor and this has led to better FDA inspection result.” Defendant Coleman also touted the growth to come from the Boston Facility in the coming years, stating that the Company’s investments into the Boston Facility and two other plants were expected to deliver “the greatest growth [] over the next 5 years.”

128. On July 29, 2021, Integra filed its quarterly report for the period ended June 30, 2021 on a Form 10-Q with the SEC (the “2Q21 10-Q”). The 2Q21 10-Q contained substantially the same materially false and misleading statements regarding the remediation efforts at the Boston Facility and the effects of the 2019 Warning Letter on the Company as the 1Q19 10-Q. See ¶ 100.

129. The 2Q21 10-Q was signed by Defendants Arduini, Anderson, and Mosebrook. The 2Q21 10-Q was also accompanied by SOX Certifications made by Defendants Arduini and Anderson, wherein they attested to the accuracy of the 2Q21 10-Q.

130. On November 2, 2021, the Company filed its quarterly report for the period ended September 30, 2021 with the SEC (the “3Q21 10-Q”). The 3Q21 10-Q contained substantially the same materially false and misleading statements regarding the remediation efforts at the Boston Facility and the effects of the 2019 Warning Letter on the Company as the 1Q19 10-Q. *See ¶ 100.*

131. The 3Q21 10-Q was signed by Defendants Arduini, Anderson, and Mosebrook. The 3Q21 10-Q was also accompanied by SOX Certifications signed by Defendants Arduini and Anderson, wherein they attested to the accuracy of the 3Q21 10-Q.

132. On February 24, 2022, the Company filed its annual report for 2021 on a Form 10-K with the SEC (the “2021 10-K”). In the 2021 10-K, Integra disclosed to investors that the FDA completed another inspection of the Boston Facility in October and November of 2021 and issued the 2021 Form 483 in connection therewith on November 12, 2021. However, in the 2021 10-K, the Company continued downplayed the effect of the 2021 Form 483 to investors, stating, in relevant part, “[t]he Warning Letter and the 2021 Form 483 do not restrict the Company’s ability to manufacture or ship products or require the recall of any products, nor do they restrict our ability to seek FDA 510(k) clearance of products.” The 2021 10-K also assured investors that remediation efforts were underway in response to the 2019 Warning Letter, stating “[t]he Company submitted its initial response to the FDA Warning Letter on March 28, 2019 and provides regular progress reports to the FDA as to its corrective actions and, since the conclusion of the inspection, has undertaken significant efforts to remediate the observations and continues to do so.”

133. The 2021 10-K was signed by Defendants De Witte, Anderson, Mosebrook, Essig, Ballintyn, Bradley, Clay, Hill, Morel, Murphy, and Schade. The 2021 10-K was also accompanied by SOX Certifications made by Defendants De Witte and Anderson, wherein they attested to the accuracy of the 2021 10-K.

134. On April 8, 2022, the Company filed its annual proxy statement for 2022 on a Schedule 14A with the SEC (the “2022 Proxy”). The 2022 Proxy contained substantially the same section on the Board’s role in risk oversight as the 2021 Proxy, stating, in relevant part:

The Board of Directors has overall responsibility for the oversight of risk management at the Company and has delegated responsibility for the oversight of certain areas of risk management to the standing Committees of the Board, as described below. Each standing Board committee reports to the full Board following each committee meeting. . . .

The Board is committed to oversight of the Company’s business strategy and strategic planning, including through the work of the Board committees and regular Board meetings. This ongoing effort enables the Board to focus on Company performance over the short, intermediate and long term. In addition to financial and operational performance, non-financial measures, including diversity and sustainability goals, are addressed by the Board and Board committees.

The Company has also implemented an Enterprise Risk Management (“ERM”) program to further enhance its oversight of risks inherent to the business. This ERM program allows the Board and management to gain a greater understanding and awareness of risks facing the business and to mitigate those risks.

In addition to periodic updates management provides to the Board on the ERM program, management presents an annual report to the Board detailing the Company’s processes for (1) assessing and addressing risks, (2) compliance reporting, and (3) the reporting of other material information.

Our President and Chief Executive Officer, who functions as our chief risk officer, has responsibility for ensuring management provides periodic updates to the Board or Board committees regarding risks in many areas, among them accounting, treasury, information systems, legal, governance, legislative (including reimbursement), general compliance (including sales and marketing compliance), quality, regulatory, sustainability, environment, social and governance (“ESG”) risks and opportunities, corporate development, operations and sales and marketing. Both formal reports and less formal communications between the Board and our President and Chief Executive Officer derive from a continual flow of

communication throughout the Company regarding risk and compliance. We believe our Board and senior management team promote a culture that actively identifies and manages risk.

The ERM program, along with our annual processes for creating and reviewing with the Board our strategic plan, budget and internal audit plans, as well as regular processes and communications throughout the Company, including between management and the Board and Board committees, combine to ensure the Company is continually addressing its business risks in a disciplined fashion

135. The 2022 Proxy again highlighted the Company's Code of Conduct and compliance efforts, stating "Integra is committed to its Code of Conduct and to holding the Company accountable as a leader in the medical technology industry. The Company operates a comprehensive compliance program, which is supported by a training program led by Integra's Chief Compliance Officer."

136. On April 27, 2022, the Company filed its quarterly report for the period ended March 31, 2022 on a Form 10-Q with the SEC (the "1Q22 10-Q"). The 1Q22 10-Q assured investors that the remediation efforts at the Boston Facility were underway and that the 2019 Warning Letter and 2021 Form 483 would not have a significant effect on the Company's business and manufacturing, stating, in relevant part:

The Company submitted its initial response to the FDA Warning Letter on March 28, 2019 and provides regular progress reports to the FDA as to its corrective actions and, since the conclusion of the inspection, ***has undertaken significant efforts to remediate the observations and continues to do so.*** On October 28, 2021 the FDA initiated an inspection of the facility and at the conclusion of the inspection issued a FDA Form 483 on November 12, 2021 (the "2021 Form 483"). The Company provided an initial response to the inspection observations and will continue to provide responses to FDA. ***The Warning Letter and the 2021 FDA Form 483 do not restrict the Company's ability to manufacture or ship products or require the recall of any products, nor do they restrict our ability to seek FDA 510(k) clearance of products.***

(Emphasis added).

137. The 1Q22 10-Q was signed by Defendants De Witte, Anderson, and Mosebrook. The 1Q22 10-Q was also accompanied by SOX Certifications signed by Defendants De Witte and Anderson, wherein they attested to the accuracy of the 1Q22 10-Q.

138. On July 27, 2022, the Company filed its quarterly report for the period ended June 30, 2022 on a Form 10-Q with the SEC (the “2Q22 10-Q”). The 2Q22 10-Q contained substantially the same materially false and misleading statements regarding the remediation efforts at the Boston Facility and the effects of the 2019 Warning Letter and 2021 Form 483 on the Company as the 1Q22 10-Q. *See ¶ 136.*

139. The 2Q22 10-Q was signed by Defendants De Witte, Anderson, and Mosebrook. The 2Q22 10-Q was also accompanied by SOX Certifications signed by Defendants De Witte and Anderson, wherein they attested to the accuracy of the 2Q22 10-Q.

140. On September 30, 2022, the Company disseminated its first ever “Environmental, Social & Governance (ESG) Report” for 2021 (the “2021 ESG Report”) to investors. The 2021 ESG Report highlighted Integra’s “deep commitment” to producing high quality and safe medical technology that were fully compliant with all regulatory requirements, which includes cGMP, stating, in relevant part, “[w]e have numerous mechanisms and processes embedded within our business operations to protect and ensure product quality, continuously improve the effectiveness of our quality management system, and ensure compliance with all regulatory requirements.” Further, the 2021 ESG Report specifically stated that “Integra adheres to good manufacturing practices (GMPs), [and] quality system regulations (QSRs).”

141. On October 26, 2022, the Company filed its quarterly report for the period ended September 30, 2022 on a Form 10-Q with the SEC (the “3Q22 10-Q”). The 3Q22 10-Q contained substantially the same materially false and misleading statements regarding the remediation efforts

at the Boston Facility and the effects of the 2019 Warning Letter and 2021 Form 483 on the Company as the 1Q22 10-Q. *See ¶ 136.*

142. The 3Q22 10-Q was signed by Defendants De Witte, Anderson, and Mosebrook. The 3Q22 10-Q was also accompanied by SOX Certifications signed by Defendants De Witte and Anderson, wherein they attested to the accuracy of the 3Q22 10-Q.

143. On February 22, 2023, the Company filed its annual report for 2022 on a Form 10-K with the SEC (the “2022 10-K”). The 2022 10-K again assured investors that Integra was on track with its remediation of the Boston Facility, stating, “[t]he Company submitted its initial response to the FDA Warning Letter on March 28, 2019 and provides regular progress reports to the FDA as to its corrective actions and, since the conclusion of the inspection, has undertaken significant efforts to remediate the observations and continues to do so.” The 2022 10-K also continued to downplay the 2021 Form 483 and the 2019 Warning Letter, stating “[t]he Warning Letter and the 2021 FDA Form 483 do not restrict the Company’s ability to manufacture or ship products or require the recall of any products, nor do they restrict our ability to seek FDA 510(k) clearance of products.”

144. The 2022 10-K was signed by Defendants De Witte, Mosebrook, Essig, Bradley, Clay, Hill, Lo, Morel, Murphy, and Schade. The 2022 10-K was also accompanied by SOX Certifications made by Defendants De Witte and Mosebrook, wherein they attested to the accuracy of the 2022 10-K.

145. On April 6, 2023, the Company filed its annual proxy statement for 2023 on a Schedule 14A with the SEC (the “2023 Proxy”). The 2023 Proxy again touted the Board’s risk oversight measures, stating, in relevant part:

The Board has overall responsibility for the oversight of risk management at the Company, which includes overseeing our process for identifying, assessing and

mitigating significant financial, operational, strategic, cybersecurity and other risks that may affect the Company. A fundamental part of risk oversight is understanding the risks that Integra faces, the steps management is taking to manage those risks, and assessing the Company's appetite for risk. The risk assessment process also considers whether risks are short-, medium-, or long-term, such that the management of significant risks can be prioritized, in part, based on the timeframe of such risks. Risk management systems, including our internal auditing procedures, internal control over financial reporting and corporate compliance programs, are designed in part to inform management about our material risks. Our Board receives regular reports from management on matters relating to strategic and operational initiatives, financial performance, cybersecurity and legal developments, including the related enterprise-risk exposures. The involvement of the Board in the oversight of our strategic planning process is a key part of its assessment of the risks inherent in our corporate strategy.

The Board has delegated responsibility for the oversight of certain areas of risk management to the standing Committees of the Board, as described below. Each standing Board committee reports to the full Board following each committee meeting. . . .

The Board is committed to oversight of the Company's business strategy and strategic planning, including through the work of the Board committees and regular Board meetings. This ongoing effort enables the Board to focus on Company performance over the short, intermediate and long term. In addition to financial and operational performance, non-financial measures, including diversity and sustainability goals, are addressed by the Board and Board committees.

The Company has also implemented an Enterprise Risk Management ("ERM") program to further enhance its oversight of risks inherent to the business. This ERM program allows the Board and management to gain a greater understanding and awareness of risks facing the business and the efforts being undertaken to mitigate those risks. Additionally, the executive leadership team's individual performance objectives are aligned with the top risks identified in the annual ERM process.

In addition to periodic updates management provides to the Board on the ERM program, management presents an annual report to the Board detailing the Company's processes for (1) assessing and addressing risks, (2) compliance reporting, and (3) the reporting of other material information.

Our President and Chief Executive Officer, who functions as our chief risk officer, is supported in this role by both our Chief Legal Officer and our Chief Compliance Officer, who reports to our Chief Legal Officer. As chief risk officer, our President and Chief Executive Officer has responsibility for ensuring management provides periodic updates to the Board or Board committees regarding risks in many areas, among them accounting, treasury, information systems, legal, governance, legislative (including reimbursement), general compliance (including sales and

marketing compliance), quality, regulatory, sustainability, ESG risks and opportunities, corporate development, operations and sales, marketing and cybersecurity. Both formal reports and less formal communications between the Board and our President and Chief Executive Officer derive from a continual flow of communication throughout the Company regarding risk and compliance. We believe our Board and senior management team promote a culture that actively identifies and manages risk.

The ERM program, along with our annual processes for creating and reviewing with the Board our strategic plan, budget and internal audit plans, as well as regular processes and communications throughout the Company, including between management and the Board and Board committees, combine to ensure the Company is continually addressing its business risks in a disciplined fashion.

146. The 2023 Proxy touted the Company's Code of Conduct and compliance efforts, stating, in relevant part:

Integra is committed to its Code of Conduct and to holding the Company accountable as a leader in the medical technology industry. The Company operates a comprehensive compliance program, which is supported by a training program led by Integra's Chief Compliance Officer. Our comprehensive Code of Conduct reflects our expectation of compliance with laws, regulations, and codes of ethics relevant to our industry around the world. This Code of Conduct is on the Integra website and applies to all individuals and organizations that are suppliers to or third-party intermediaries for Integra. It establishes minimum requirements and expectations for the conduct of Integra's business partners, and Integra encourages its partners to establish stricter or more extensive requirements where appropriate.

147. On April 26, 2023, the Company hosted an earnings call for investors and analysts to discuss its financial results for the first quarter of 2023 (the "1Q23 Earnings Call"). During the 1Q23 Earnings Call, Defendant De Witte assured investors that the deficiencies identified by the FDA were actively being remediated, stating, in relevant part, that the Company has "been working for the "past couple of years to upgrade [the] Boston [F]acility based on FDA observations in 2018 and 2021," and that the Company "had an audit early in March that confirms we're on the right track with our execution."

148. On the same day, the Company filed its quarterly report for the period ended March 31, 2023 on a Form 10-Q with the SEC (the "1Q23 10-Q"). The 1Q23 10-Q contained substantially

the same materially false and misleading statements regarding the remediation efforts at the Boston Facility and the effects of the 2019 Warning Letter and 2021 Form 483 on the Company as the 1Q22 10-Q. *See ¶ 136.*

149. The 1Q23 10-Q was signed by Defendants De Witte and Mosebrook. The 1Q23 10-Q was also accompanied by SOX Certifications signed by Defendants De Witte and Mosebrook, wherein they attested to the accuracy of the 1Q23 10-Q.

150. On May 4, 2023, at Integra’s Analyst/Investor Day, Defendant Leonard touted the Company’s work towards making the Boston Facility cGMP-compliant, stating, in relevant part, “[l]ast year and this year, we made significant investments in quality across all of our manufacturing sites with a focus on accelerating our quality project in Boston involving testing, infrastructure, and physical layout changes.” Defendant Leonard went on to highlight the Company’s production of biologic mesh products, stating, in relevant part, “the relocation of our Boston facility to a new PMA-ready site in nearby Braintree will more than double our capacity for SurgiMend and PriMatrix in 2025.”

151. On July 27, 2023, the Company hosted an earnings call for investors and analysts to discuss its financial results for the second quarter of 2023 (the “2Q23 Earnings Call”). During the 2Q23 Earnings Call, Defendant De Witte again assured investors that the Company was on track with its remediation efforts at the Boston Facility, stating that “we have no specific indications of any product complaints related to high endotoxin levels,” that “[p]atient safety is non-negotiable” for the Company, and that the Company was “highly focused on our remediation efforts” and “fully expect[ed] to complete the remediation.”

152. On the same day, the Company filed its quarterly report for the period ended June 30, 2023 on a Form 10-Q with the SEC (the “2Q23 10-Q”). In the 2Q23 10-Q, the Company

discussed the 2023 Warning Letter and 2023 Form 483. However, the 2Q23 assured investors that the remediation efforts at the Boston Facility were underway and continued to downplay the impact of the FDA's findings, stating, in relevant part:

On March 1, 2023, the FDA commenced an inspection of the Boston facility, and issued an FDA Form 483 at the conclusion of this inspection (the "2023 Form 483"). On July 19, 2023, TEI received a Warning Letter, dated July 17, 2023, from the FDA related to quality system issues at the TEI Boston facility (the "2023 Warning Letter"). The 2023 Warning Letter did not identify any new observations that had not already been provided in the 2023 Form 483. The Company submitted an initial response to the 2023 Form 483 to the FDA and is in the process of preparing a written response to the 2023 Warning Letter. ***We are committed to resolving the matters identified in the Warning Letters and Form 483s and are continuing our significant efforts to remediate the observations. Although the Warning Letters and the Form 483s do not restrict our ability to manufacture or ship products or require the recall of any products***, in May 2023, after consultation with the FDA, the Company initiated a voluntary recall of products manufactured in the Boston facility distributed between March 1, 2018 and May 22, 2023, and extended the temporary halt of manufacturing at the facility to implement additional detection and quality controls. ***Following implementation of such controls, the Company expects to resume manufacturing at its Boston facility by late in the fourth quarter of 2023. Additionally, the Warning Letters do not restrict the Company's ability to seek FDA 510(k) clearance of products. . . .***

(Emphasis added).

153. The 2Q23 10-Q was signed by Defendants De Witte, Knight, and Mosebrook. The 2Q23 10-Q was also accompanied by SOX Certifications signed by Defendants De Witte and Knight, wherein they attested to the accuracy of the 2Q23 10-Q.

154. On August 17, 2023, Integra published its Environmental, Social and Governance Report for 2022 (the "2022 ESG Report"). The 2022 ESG Report again touted the Company's efforts to comply with cGMP and improve its quality systems. The 2022 ESG Report stated, in relevant part, that "product safety and quality are paramount" to Integra and that the Company "continuously improve[s] our Quality Management System (QMS) to meet the highest and most current quality standards." The 2022 ESG Report also stated that "[t]o avoid defects and deliver

the highest-quality products, Integra also adheres to Good Manufacturing Practices (GMPs), [and] Quality System Regulations (QSRs).”

155. On September 6, 2023, Defendant Knight attended the Wells Fargo Securities Healthcare Conference on behalf of Integra and assured investors and analysts that the remediation efforts at the Boston Facility were on track. In response to an analyst question about production and the Recall, Defendant Knight assured investors that the “Boston remediation continues to progress well” and that the Company “hired in the right technical expertise to support and drive building a remediation plan and executing against it... ***we are absolutely on the right path, that our timelines to get back into market are real.***” (Emphasis added). Defendant Knight went on to tell investors that the Company would “begin manufacturing again in the end of this year and that commercial distribution would resume somewhere in the mid to late Q2 2024 timeline.”

156. On October 25, 2023, the Company hosted an earnings call for investors and analysts to discuss its financial results for the third quarter of 2023 (the “Q323 Earnings Call”). During the Q323 Earnings Call, Defendant De Witte assured investors that Integra made significant progress in the remediation efforts at the Boston Facility, stating, in relevant part, “***our progress in addressing the Boston facility and returning to the market remains on track.*** Interim external reviews ***confirm the adequacy of our remediation plan*** and the changes made so far and they ***reflect significant steps made towards the resumption of manufacturing by the end of the fourth quarter 2023 and commercial distribution in mid- to late second quarter ‘24.***” (Emphasis added). Defendant De Witte went on to state that “we are on track with our communicated timeline.”

157. On the same day, the Company filed its quarterly report for the period ended September 30, 2023 on a Form 10-Q with the SEC (the “3Q23 10-Q”). The 3Q23 10-Q contained

substantially the same materially false and misleading statements regarding the remediation efforts at the Boston Facility and the effects of the 2019 Warning Letter, 2021 Form 483, 2023 Form 483, and 2023 Warning Letter on the Company as the 2Q23 10-Q. *See ¶ 152.*

158. The 3Q23 10-Q was signed by Defendants De Witte, Knight, and Mosebrook. The 3Q23 10-Q was also accompanied by SOX Certifications signed by Defendants De Witte and Knight, wherein they attested to the accuracy of the 3Q23 10-Q.

159. On February 28, 2024, Integra issued a press release announcing its financial results for the fourth quarter and full year of 2023 (the “4Q23 Earnings Release”). In the 4Q23 Earnings Release, the Company assured investors that remediation efforts were on track, stating that “[r]elaunch remains on track for mid-to-late Q2 2024.”

160. On the same day, the Company hosted an earnings call for investors and analysts to discuss its financial results for the fourth quarter of 2023 (the “4Q23 Earnings Call”). During the 4Q23 Earnings Call, Defendant De Witte assured investors that the Boston Facility’s reopening was on track, stating, in relevant part:

So on Boston, just as a reminder, we restarted that factory in November and then in January had an external review, which we call the dress rehearsal. ***I call it a successful dress rehearsal because what we got were the confirmations***, but also the learnings that we hoped to get based on the work done and its guidance, the learnings have been guiding us since the end of January over February into the preparation for that external audit, which will take place in March.

The audits pretty much cover every aspect of our quality management system, I mean, from beginning to end. ***We got, I would say, limited observations on things that we could have improved.*** . . .

And that's why we called it a dress rehearsal. Part of successful audit is not just having your quality management system processes documentation where it needs to be. It's also making sure that in the question and answering with the auditors, you make sure that all that work is readily visible.

161. De Witte then assured investors that “[s]uccessful audit will allow us to start building finished goods inventory to resume distribution mid- to late second quarter.”

162. Also on February 28, 2024, Integra filed its annual report for 2023 on a Form 10-K with the SEC (the “2023 10-K”). The 2023 10-K discussed the Recall of the products manufactured at the Boston Facility, stating “in May 2023, after consultation with the FDA, we initiated a voluntary global recall of all products manufactured in our Boston, Massachusetts facility distributed between March 1, 2018 and May 22, 2023.” However, the 2023 10-K again downplayed the impact of this on the Company, stating, that they undertook “remediation efforts” for the Boston Facility and had “expectations regarding the resumption of commercial distribution of products manufactured at the Boston facility.”

163. The 2023 10-K also discussed the 2023 Form 483 and the 2023 Warning Letter from the FDA and assured investors that Integra was taking the proper steps to remediate the issues, stating, in relevant part:

On March 1, 2023, the FDA commenced an inspection of the Boston facility, and issued an FDA Form 483 at the conclusion of this inspection (the “2023 Form 483”). In May 2023, after consultation with the FDA, the Company initiated a voluntary recall of products manufactured in the Boston facility distributed between March 1, 2018 and May 22, 2023, and extended the temporary halt of manufacturing at the facility to implement additional detection and quality controls. On July 19, 2023, TEI received a Warning Letter, dated July 17, 2023, from the FDA related to quality system issues at the Boston facility (the “2023 Warning Letter”). The 2023 Warning Letter did not identify any new observations that had not already been provided in the 2023 Form 483. The Company has submitted an initial response to the FDA for both the 2023 Form 483 and the 2023 Warning Letter. ***We committed to resolving the matters identified in the Warning Letters and Form 483s and are continuing our significant efforts to remediate the observations.***

(Emphasis added).

164. The 2023 10-K was signed by Defendants De Witte, Knight, Mosebrook, Essig, Bradley, Clay, Graves, Hill, Lo, Murphy, and Schade. The 2023 10-K was also accompanied by

SOX Certifications made by Defendants De Witte and Knight, wherein they attested to the accuracy of the 2023 10-K.

165. On April 4, 2024, the Company filed its annual proxy statement for 2024 on a Schedule 14A with the SEC (the “2024 Proxy”). The 2024 Proxy again touted the Company’s risk oversight measures, stating, in relevant part:

The Board has overall responsibility for the oversight of risk management at the Company, which includes overseeing our process for identifying, assessing and mitigating significant financial, operational, strategic, cybersecurity and other risks that may affect the Company. A fundamental part of risk oversight is understanding the risks that Integra faces, the steps management is taking to manage those risks, and assessing the Company's appetite for risk. The risk assessment process also considers whether risks are short-, medium-, or long-term, such that the management of significant risks can be prioritized, in part, based on the timeframe of such risks. Risk management systems, including our internal auditing procedures, internal control over financial reporting and corporate compliance programs, are designed in part to inform management about our material risks. Our Board receives regular reports from management on matters relating to strategic and operational initiatives, financial performance, cybersecurity and legal developments, including the related enterprise-risk exposures. The involvement of the Board in the oversight of our strategic planning process is a key part of its assessment of the risks inherent in our corporate strategy.

The Board has delegated responsibility for the oversight of certain areas of risk management to the standing Committees of the Board, as described below. Each standing Board committee reports to the full Board following each committee meeting. . . .

The Board is committed to oversight of the Company’s business strategy and strategic planning, including through the work of the Board committees and regular Board meetings. This ongoing effort enables the Board to focus on Company performance over the short, intermediate and long term. In addition to financial and operational performance, non-financial measures, including diversity and sustainability goals, are addressed by the Board and Board committees.

The Company has also implemented an Enterprise Risk Management (“ERM”) program to further enhance its oversight of risks inherent to the business. This ERM program allows the Board and management to gain a greater understanding and awareness of risks facing the business and the efforts being undertaken to mitigate those risks. Additionally, the executive leadership team’s individual performance objectives are aligned with the top risks identified in the annual ERM process.

In addition to periodic updates management provides to the Board on the ERM program, management presents an annual report to the Board detailing the Company's processes for (1) assessing and addressing risks, (2) compliance reporting, and (3) the reporting of other material information.

Our President and Chief Executive Officer, who functions as our chief risk officer, is supported in this role by both our Chief Legal Officer and our Chief Compliance Officer, who reports to our Chief Legal Officer. As chief risk officer, our President and Chief Executive Officer has responsibility for ensuring management provides periodic updates to the Board or Board committees regarding risks in many areas, among them accounting, treasury, information systems, legal, governance, legislative (including reimbursement), general compliance (including sales and marketing compliance), quality, regulatory, sustainability, ESG risks and opportunities, corporate development, operations and sales, marketing and cybersecurity. Both formal reports and less formal communications between the Board and our President and Chief Executive Officer derive from a continual flow of communication throughout the Company regarding risk and compliance. We believe our Board and senior management team promote a culture that actively identifies and manages risk.

The ERM program, along with our annual processes for creating and reviewing with the Board our strategic plan, budget and internal audit plans, as well as regular processes and communications throughout the Company, including between management and the Board and Board committees, combine to ensure the Company is continually addressing its business risks in a disciplined fashion.

166. The 2024 Proxy Statement also touted the Company's Code of Conduct and its compliance program, stating, in relevant part:

Integra is committed to its Code of Conduct and to holding the Company accountable as a leader in the medical technology industry. The Company operates a comprehensive compliance program, which is supported by a training program led by Integra's Chief Compliance Officer. Our comprehensive Code of Conduct reflects our expectation of compliance with laws, regulations, and codes of ethics relevant to our industry around the world. This Code of Conduct is on the Integra website and applies to all individuals and organizations that are suppliers to or third-party intermediaries for Integra. It establishes minimum requirements and expectations for the conduct of Integra's business partners, and Integra encourages its partners to establish stricter or more extensive requirements where appropriate.

167. On May 6, 2024, the Company issued its quarterly report for the period ended March 31, 2024 on a Form 10-Q with the SEC (the "1Q24 10-Q"). The 1Q24 10-Q contained substantially the same materially false and misleading statements regarding the remediation efforts

at the Boston Facility and the effects of the 2019 Warning Letter, 2021 Form 483, 2023 Form 483, and 2023 Warning Letter on the Company as the 2Q23 10-Q. *See ¶ 152.* The 1Q24 10-Q also revealed that, “[f]ollowing implementation of upgraded Good Laboratory Practices and expertise and a standardization of corrective and preventative action processes and governance, the Company resumed manufacturing at its Boston facility in the fourth quarter of 2023.”

168. The 1Q24 10-Q was signed by Defendants De Witte, Knight, and Mosebrook. The 1Q24 10-Q was also accompanied by SOX Certifications signed by Defendants De Witte and Knight, wherein they attested to the accuracy of the 1Q24 10-Q.

169. The above statements were materially false and/or misleading and failed to disclose material adverse facts about the Company’s business, operations, and prospects. Specifically, the Individual Defendants failed to disclose to investors, *inter alia*, that: (a) the Company was not taking meaningful efforts to address the systemic cGMP deficiencies at the Boston Facility; (b) the Company did not comply with cGMP in the manufacturing of SurgiMend, PriMatrix, and other EBM products; (c) the Company did not have proper internal mechanisms and processes in place to ensure compliance with cGMP; (d) the cGMP violations that led to the FDA investigations and findings impacted the Company’s ability to manufacture EBM products at the Boston Facility; (e) the Company did not have effective risk oversight mechanisms in place; and (f) as a result of the foregoing, the Company’s public statements regarding its business, operations, and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

The Truth is Revealed

170. The truth began to emerge on February 28, 2024, when the Company announced that Integra was experiencing significant declines in its financial performance due to the forced shutdown and remediation at the Boston Facility and that Defendant De Witte was departing the

Company.

171. The Company issued a press release on February 28, 2024, announcing that Defendant De Witte informed the Board of his intention to retire from the Company by the end of 2024. On the same day, the Company also issued the 4Q23 Earnings Release, wherein Integra revealed disappointing financial results for the fourth quarter and full year of 2023, reporting that the Company's 2023 earnings were negatively impacted by issues at the Boston Facility, including (a) a 7.7% decline in adjusted earnings per share ("EPS") due to spending reductions, (b) a 62% decline in GAAP net income, (c) an 11.7% decline in adjusted net income due to product returns, unfavorable mix from the lost revenue and remediation costs, and (d) a 24% decline in adjusted EBITDA margins due to the recall. The 4Q23 Earnings Release also announced disappointing guidance for the first quarter and full year of 2024, including an anticipated decline in revenues from 5.5% to 4.1% for the first quarter 2024, as well as reductions attributable to the cessation of any new orders for private label products manufactured at the Boston Facility.

172. Furthermore, during the 4Q23 Earnings Call on February 28, 2024, Defendant De Witte revealed, "[t]he Boston recall weighed on our financial results for the year." Defendant Knight went on to reveal, in relevant part:

The second theme was the impact of the Boston recall, which drove significant operational challenges in 2023. Our full year revenues were \$1.542 billion, down approximately 1% on a reported basis, with organic growth flat for the year and within our guidance range communicated in October. The Boston recall represented an approximate \$67 million headwind to our reported revenues.

173. On this news, the Company's stock price fell \$5.60 per share, or approximately 13%, to close at \$38.67 per share on February 28, 2024.

174. Then, on May 6, 2024, the Company announced that the Company's EPS guidance for 2024 decreased and that the Boston Facility shutdown would need to be extended for another

seven months, bringing the total shutdown time to *over a year and a half*.

175. In its press release announcing Integra’s financial results for the first quarter of 2024 (the “1Q24 Earnings Release”), the Company announced that it cut the Company’s full year adjusted EPS guidance from a range of \$3.15 to \$3.20 per share, to \$3.01 to \$3.11 per share, well below analysts’ consensus estimate of \$3.19 per share.

176. On the same day, during its earnings call with analysts and investors to discuss the Company’s financial results for the first quarter of 2024 (the “1Q24 Earnings Call”), Defendant De Witte revealed, “[b]ased on our preliminary assessment, we no longer expect to resume commercial distribution in 2024,” bringing the total shutdown of the Boston Facility to over a year and a half. Defendant De Witte also stated that the reduction in EPS for 2024 “reflect[s] the delay of the relaunch of SurgiMend and PriMatrix.”

177. On this news, the Company’s stock price fell \$5.75 per share, or approximately 20%, to close at \$23.14 per share on May 6, 2024.

178. The truth about the Company’s cGMP violations fully emerged on July 29, 2024, when Integra revealed that there were cGMP deficiencies and shipping holds across all of the Company’s facilities, which required the Company to implement a Company-wide “compliance master plan to address quality systems and cGMP learnings.”

179. The Company issued a press release announcing its financial results for the second quarter of 2024 (the “2Q24 Earnings Release”). In the 2Q24 Earnings Release, Integra revealed that it was “[i]mplementing compliance master plan to address quality system and GMP compliance learnings. As a result, the company has initiated temporary shipping holds on certain products that will primarily impact the third quarter.” The Company’s quarterly report for the second quarter of 2024 filed on a Form 10-Q on the same day (the “2Q24 10-Q”) revealed further

details on the compliance master plan, stating:

In Q2 2024, we initiated the planning of a Compliance Master Plan (the “CMP”), a systematic and holistic approach to improving our quality system and Good Manufacturing Practice (“GMP”) compliance for the Boston/Braintree sites. While the initial planning has been implemented for the Boston/Braintree sites, the CMP will be expanded across our manufacturing and supply network in the coming months to ensure we can sustain compliance and enable our product supply to match our customer demand. We expect the CMP implementation and engagement to last through 2025.

180. The Company also held an earnings call to discuss the financial results for the second quarter of 2024 on the same day (the “2Q24 Earnings Call”). During the 2Q24 Earnings Call, Defendants De Witte and Essig made statements regarding the compliance master plan. Defendant Essig stated that it was “clear that there is a need to bolster our manufacturing quality compliance processes across the organization” and that management was finally “giving these issues the attention they deserve.” During the 2Q24 Earnings Call, Defendant Knight also revealed that the compliance master plan, and the resulting shipping holds, resulted in reduced forecasted revenues “in the range of \$1.609 billion to \$1.629 billion,” a reduction of approximately \$90 million.

181. On this news, the Company’s stock price fell \$6.01 per share, or approximately 19%, to close at \$25.42 per share on July 29, 2024.

Insider Sales

182. During the Relevant Period, Defendants Schade, Coleman, Murphy, Arduini, Essig, and Mosebrook made sales of Integra’s common stock while in possession of non-public information concerning the Company’s business prospects and financial condition.

183. While the Company’s stock price was artificially inflated, Defendant Schade sold approximately 15,658 shares of Integra common stock, totaling proceeds of over \$807,326. Defendant Schade made the following sales of Integra stock during the Relevant Period:

Transaction Date	Number of Shares Sold	Average Price Per Share	Total Transaction
5/10/2019	15,658	\$51.56	\$807,326.48

184. While the Company's stock price was artificially inflated, Defendant Coleman sold approximately 80,000 shares of Integra common stock, totaling proceeds of over \$5.4 million. Defendant Coleman made the following sales of Integra stock during the Relevant Period:

Transaction Date	Number of Shares Sold	Average Price Per Share	Total Transaction
6/28/2019	3,650	\$55.00	\$200,750
4/24/2019	3,500	\$57.50	\$201,250
8/11/2020	5,000	\$52.27	\$261,350
3/29/2021	15,500	\$68.50	\$1,061,750
4/9/2021	12,500	\$70.00	\$875,000
4/14/2021	4,002	\$70.50	\$282,141
4/16/2021	25,658	\$71.50	\$1,834,547
11/2/2021	4,275	\$74.00	\$316,350
4/4/2022	6,628	\$66.04	\$413,938.72

185. While the Company's stock price was artificially inflated, Defendant Murphy sold approximately 12,136 shares of Integra common stock, totaling proceeds of nearly \$700,000. Defendant Murphy made the following sales of Integra stock during the Relevant Period:

Transaction Date	Number of Shares Sold	Average Price Per Share	Total Transaction
8/16/2019	4,136	\$60.99	\$252,254.64
8/5/2022	8,000	\$55.78	\$446,240

186. While the Company's stock price was artificially inflated, Defendant Arduini sold approximately 282,316 shares of Integra common stock, totaling proceeds of over \$16.9 million. Defendant Arduini made the following sales of Integra stock during the Relevant Period:

Transaction Date	Number of Shares Sold	Average Price Per Share	Total Transaction
9/6/2019	250,000	\$60.55	\$15,137,500
2/26/2020	32,316	\$55.68	\$1,799,354.88

187. While the Company's stock price was artificially inflated, Defendant Essig sold

approximately 275,073 shares of Integra common stock, totaling proceeds of over \$17.75 million.

Defendant Essig made the following sales of Integra stock during the Relevant Period:

Transaction Date	Number of Shares Sold	Average Price Per Share	Total Transaction
5/12/2020	2,087	\$52.07	\$108,670.09
5/26/2020	46,807	\$52.08	\$2,437,708.56
5/28/2020	11,626	\$52.40	\$609,202.40
3/18/2021	214,553	\$68.14	\$14,619,641.42

188. While the Company's stock price was artificially inflated, Defendant Mosebrook sold approximately 1,774 shares of Integra common stock, totaling proceeds of over \$113,178.

Defendant Mosebrook made the following sales of Integra stock during the Relevant Period:

Transaction Date	Number of Shares Sold	Average Price Per Share	Total Transaction
3/2/2021	1,058	\$68.70	\$72,684.40
8/2/2022	437	\$56.77	\$24,808.49
12/8/2022	279	\$56.22	\$15,685.38

189. As a result of these insider sales, Defendants Schade, Coleman, Murphy, Arduini, Essig, and Mosebrook were unjustly enriched.

Harm to the Company

190. As a direct and proximate result of the Individual Defendants' misconduct, Integra has lost and expended, and will lose and expend, millions of dollars.

191. Such expenditures include, but are not limited to, the legal fees associated with the Securities Class Action filed against the Company and Defendants Anderson, Arduini, Coleman, Davis, De Witte, Knight, Leonard, and Mosebrook, and amounts paid to outside lawyers, accountants, and investigators in connection therewith.

192. Such expenditures also include, but are not limited to, significant compensation and benefits paid to the Individual Defendants who breached their fiduciary duties to the Company.

193. Furthermore, the Securities Class Action has exposed the Company to massive

class-wide liability.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

194. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties by the Individual Defendants.

195. Plaintiff will adequately and fairly represent the interests of Integra and its shareholders in enforcing and prosecuting its rights.

196. Integra is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would otherwise not have.

197. Plaintiff is a current shareholder of Integra and was a continuous shareholder of the Company during the period of the Individual Defendants' wrongdoing alleged herein. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights and retained counsel competent and experienced in derivative litigation.

198. A pre-suit demand on the Board of Integra is futile and, therefore, excused. At the time this action was commenced, the nine-person Board consisted of Individual Defendants Essig, Bradley, Clay, Hill, Graves, Lo, Murphy, and Schade (the "Director Defendants") and non-party Mojedh Poul ("Poul," and together with the Director Defendants, the "Directors"). Accordingly, Plaintiff is only required to show that five Directors cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. As set forth below, all of the Directors are incapable of making an independent and disinterested decision to institute and vigorously prosecute this action because they face a substantial likelihood of liability for the misconduct alleged herein. Therefore, demand on the Board to institute this action is not necessary because such a demand would have been a futile and useless act.

199. The Director Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.

200. Each of the Director Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.

201. Each of the Individual Defendants authorized and/or permitted the false statements to be disseminated directly to the public and made available and distributed to shareholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.

202. As members of the Board charged with overseeing the Company's affairs, each of the Director Defendants had knowledge, or the fiduciary obligation to inform themselves, of information pertaining to the Company's core operations and the material events giving rise to these claims. Specifically, as Board members of Integra, the Director Defendants knew, or should have known, the material facts surrounding Integra's financial condition and internal control mechanisms.

203. Defendant Essig is not disinterested or independent. Defendant Essig serves as Executive Chairman of the Board. Thus, as stated in the 2024 Proxy, the Company admits that Defendant Essig is a non-independent director.

204. Director Poul is not disinterested or independent. In addition to being a director, Poul also serves as CEO and President of the Company. Thus, the Company admits that Defendant

Essig is a non-independent director.

205. Moreover, Director Defendants Essig, Bradley, Hill, Murphy, and Schade signed the 2019 10-K, 2020 10-K, 2021 10-K, 2022 10-K, and 2023 10-K, Director Defendant Clay signed the 2021 10-K, 2022 10-K, and 2023 10-K, Director Defendant Lo signed the 2022 10-K and 2023 10-K, and Director Defendant Graves signed the 2023 10-K. Accordingly, these Director Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not independent or disinterested, and thus demand upon them is futile, and, therefore, excused.

206. Additionally, each of the Director Defendants received payments, benefits, stock options, and other emoluments by virtue of their membership on the Board and their control of the Company. Furthermore, Defendants Schade, Murphy, and Essig each made insider sales of the Company's common stock while the price was artificially inflated as a result of the materially false and misleading statements alleged herein.

207. Moreover, the Director Defendants willfully ignored, or recklessly failed to inform themselves of, the obvious problems with the Company's internal controls, practices, and procedures and failed to make a good faith effort to correct the problems or prevent their recurrence. As a result of the foregoing, the Director Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

208. Additionally, the Director Defendants took no action to redress the harm suffered by the Company resulting from the misconduct alleged herein.

209. Defendants Clay, Murphy, and Schade (the "Audit Defendants") serve on the Company's Audit Committee, and pursuant to the Audit Committee Charter, were specifically charged with the responsibility to assist the Board in fulfilling its oversight responsibilities related

to, *inter alia*, financial reporting and the underlying internal controls and procedures over financial reporting. At all relevant times, however, the Audit Defendants breached their fiduciary duty to the Company by failing to prevent, correct, or inform the Board of the issuance of material misstatements and omissions regarding the Company's business, finances, and operations, as alleged above. Therefore, the Audit Defendants cannot independently consider any demand to sue themselves for breaching their fiduciary duties to the Company, as that would expose them to substantial liability and threaten their livelihoods.

210. The Director Defendants, as members of the Board, were and are subject to the Company's Code of Conduct. The Code of Conduct goes well beyond the basic fiduciary duties required by applicable laws, rules, and regulations, requiring the Director Defendants to also adhere to the Company's standards of business conduct. The Director Defendants violated the Code of Conduct because they knowingly or recklessly participated in making and/or causing the Company to make the materially false and misleading statements alleged herein. Because the Director Defendants violated the Code of Conduct, they face a substantial likelihood of liability for breaching their fiduciary duties, and therefore demand upon them is futile.

211. Accordingly, a pre-suit demand on the Board is futile and excused.

COUNT I
**Against the Individual Defendants for Violations of § 14(a)
of the Exchange Act, 15 U.S.C. § 78n(a) and Rule 14a-9 (17 C.F.R. § 240.14a-9)**

212. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

213. The Individual Defendants violated Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), and Rule 14a-9, 17 C.F.R. § 240.14a-9, promulgated thereunder by the SEC.

214. Section 14(a) of the Exchange Act provides that:

It shall be unlawful for any person, by use of the mails or by means of instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 781].

15 U.S.C. § 78n(a).

215. Rule 14a-9, promulgated pursuant to Section 14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading[.]” 17 C.F.R. § 240.14a-9.

216. The Individual Defendants, individually and in concert, disseminated and/or permitted the dissemination of materially false and misleading statements in the 2019 Proxy, 2020 Proxy, 2021 Proxy, 2023 Proxy, and 2024 Proxy (collectively, the “Proxy Statements”), which were all filed with the SEC. As alleged above, the Proxy Statements were materially false and misleading because it failed to disclose, *inter alia*, that the Board and management were not properly overseeing risks to the Company, namely risks related to cGMP compliance at its manufacturing facilities, and that the Board and management were not adhering to the Code of Conduct.

217. The misrepresentations and omissions in the Proxy Statements were material to Company stockholders. Specifically, the misrepresentations and omissions were material to Company stockholders in voting on matters set forth for shareholder determination in the Proxy Statements, including, but not limited to, the reelection of certain of the Defendants to the Board.

218. The materially false and misleading statements contained in the 2019 Proxy and

2020 Proxy misleadingly induced shareholders to vote for the reelection of Defendants Arduini, Ballintyn, Bradley, Essig, Hill, Howell, Morel, Murphy, and Schade to the Board, thereby allowing them to continue breaching their fiduciary duties to the Company.

219. The materially false and misleading statements contained in the 2021 Proxy misleadingly induced shareholders to vote for the reelection of Defendants Arduini, Ballintyn, Bradley, Clay, Essig, Hill, Morel, Murphy, and Schade to the Board, thereby allowing them to continue breaching their fiduciary duties to the Company.

220. The materially false and misleading statements contained in the 2022 Proxy misleadingly induced shareholders to vote for the reelection of Defendants Bradley, Clay, De Witte, Essig, Hill, Morel, Murphy, and Schade to the Board, thereby allowing them to continue breaching their fiduciary duties to the Company.

221. The materially false and misleading statements contained in the 2023 Proxy misleadingly induced shareholders to vote for the reelection of Defendants Bradley, Clay, De Witte, Essig, Hill, Lo, Murphy, and Schade to the Board, thereby allowing them to continue breaching their fiduciary duties to the Company.

222. The materially false and misleading statements contained in the 2024 Proxy misleadingly induced shareholders to vote for the reelection of Defendants Bradley, Clay, De Witte, Essig, Graves, Hill, Lo, Murphy, and Schade to the Board, thereby allowing them to continue breaching their fiduciary duties to the Company.

223. The Company was damaged as a result of the Defendants' material misrepresentations and omissions in the Proxy Statements.

224. As a result of the Individual Defendants' material misrepresentations and omissions, the Company has sustained significant damages.

225. Plaintiff, on behalf of Integra, has no adequate remedy at law.

COUNT II
Against the Individual Defendants
For Breach of Fiduciary Duty

226. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

227. The Individual Defendants owed the Company fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

228. Each of the Individual Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, good faith, loyalty, oversight, and supervision.

229. The Individual Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Individual Defendants breached their fiduciary duties of loyalty and good faith by permitting the use of inadequate practices and procedures to guide the truthful dissemination of Company news to the investing public and to the Company's shareholders, allowing or permitting false and misleading statements to be disseminated in the Company's SEC filings and other disclosures, and otherwise failing to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

230. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and/or misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (a) the Company was not taking meaningful efforts to remediate the systemic cGMP deficiencies at the Boston Facility; (b) the Company did not comply with cGMP

in the manufacturing of SurgiMend, PriMatrix, and other EBM products; (c) the Company did not have proper internal mechanisms and processes in place to ensure compliance with cGMP; (d) the cGMP violations that led to the FDA investigations and findings impacted the Company's ability to manufacture EBM products at the Boston Facility; (e) the Company did not have effective risk oversight mechanisms in place; and (f) as a result of the foregoing, the Company's public statements regarding its business, operations, and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

231. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent scheme set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent scheme and to fail to maintain adequate internal controls, even though such facts were available to them. The Individual Defendants, in good faith, should have taken appropriate action to correct the scheme alleged herein and to prevent it from continuing to occur.

232. In further breach of their fiduciary duties, the Individual Defendants failed to correct and/or caused the Company to fail to correct the false and/or misleading statements and omissions of material fact referenced herein.

233. As a direct and proximate result of the Individual Defendants' failure to fulfill their fiduciary obligations, the Company has sustained significant damages.

234. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company. As a direct and proximate result of the Individual Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs incurred in defending itself in the Securities Class Action, exposing the Company to millions of dollars in potential class-wide

damages in the Securities Class Action, and damage to the share price of the Company's stock, resulting in an increased cost of capital, and reputational harm.

235. Plaintiff, on behalf of Integra, has no adequate remedy at law.

COUNT III
**Against the Individual Defendants for Aiding and
Abetting Breach of Fiduciary Duty**

236. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

237. By encouraging and accomplishing the illegal and improper transactions alleged herein and concealing them from the public, the Individual Defendants have each encouraged, facilitated, and advanced their breaches of their fiduciary duties. In so doing, the Individual Defendants have each aided and abetted, conspired, and schemed with one another to breach their fiduciary duties, waste the Company's corporate assets, and engage in the ultra vires and illegal conduct complained of herein.

238. Plaintiff on behalf of Integra has no adequate remedy at law.

COUNT IV
Against the Individual Defendants for Unjust Enrichment

239. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

240. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Integra.

241. The Individual Defendants either benefitted financially from the improper conduct, or received bonuses, stock options, or similar compensation from Integra that was tied to the

performance or artificially inflated valuation of Integra, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.

242. Plaintiff, as a shareholder and a representative of Integra, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, benefits and other compensation procured by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.

243. Plaintiff on behalf of Integra has no adequate remedy at law.

COUNT V
Against the Individual Defendants for Waste of Corporate Assets

244. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

245. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the time period in issue. It resulted in continuous, connected, and ongoing harm to the Company.

246. As a result of the misconduct described above, the Individual Defendants wasted corporate assets by, *inter alia*: (i) paying and collecting excessive compensation and bonuses; and (ii) incurring potentially millions of dollars of legal liability and/or legal costs, including defending against the Securities Class Action.

247. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.

248. Plaintiff, on behalf Integra, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Awarding money damages against all Individual Defendants, jointly and severally,

for all losses and damages suffered as a result of the acts and transactions complained of herein, together with pre-judgment interest, molded in a fashion to ensure the Individual Defendants do not participate therein or benefit thereby;

B. Directing all Individual Defendants to account for all damages caused by them and all profits and special benefits and unjust enrichment they have obtained as a result of their unlawful conduct, including all salaries, bonuses, fees, stock awards, options and common stock sale proceeds, and imposing a constructive trust thereon;

C. Awarding punitive damages;

D. Awarding costs and disbursements of this action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all claims set forth herein.

DATED: February 21, 2025

RIGRODSKY LAW, P.A.

By: /s/ Gina M. Serra

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